Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
1. Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease (version 2012). *Eur Heart J.* 2012;33(19):2451-2496.	Review/Other-Dx	N/A	To provide guidelines on the management of valvular heart disease.	No results stated in abstract.	4
2. Baumgartner H, Hung J, Bermejo J, et al. Echocardiographic assessment of valve stenosis: EAE/ASE recommendations for clinical practice. *J Am Soc Echocardiogr.* 2009;22(1):1-23; quiz 101-102.	Review/Other-Dx	N/A	To detail the recommended approach to the echocardiographic evaluation of valve stenosis, including recommendations for specific measures of stenosis severity, details of data acquisition and measurement, and grading of severity.	No results stated in abstract.	4
3. Bonow RO, Carabello BA, Chatterjee K, et al. 2008 focused update incorporated into the ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to revise the 1998 guidelines for the management of patients with valvular heart disease). Endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *J Am Coll Cardiol.* 2008;52(13):e1-142.	Review/Other-Dx	N/A	To provide guidelines for the management of patients with valvular heart disease.	No results stated in abstract.	4
4. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2014;63(22):e57-185.	Review/Other-Dx	N/A	To provide guidelines for the management of patients with valvular heart disease.	No results stated in abstract.	4
5. Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease (version 2012): the Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur J Cardiothorac Surg.* 2012;42(4):S1-44.	Review/Other-Dx	N/A	To provide guidelines on the management of valvular heart disease (2012).	No results stated in abstract.	4

Imaging for Transcatheter Aortic Valve Replacement
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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
6. Bach DS, Cimino N, Deeb GM. Unoperated patients with severe aortic stenosis. *J Am Coll Cardiol.* 2007;50(20):2018-2019.	Review/Other-Dx	N/A	Summary of reasons why adult patients in the U.S. with severe AS did not undergo AVR.	No results stated in abstract.	4
7. Dua A, Dang P, Shaker R, Varadarajan P, Pai RG. Barriers to surgery in severe aortic stenosis patients with Class I indications for aortic valve replacement. *J Heart Valve Dis.* 2011;20(4):396-400.	Review/Other-Tx	187 consecutive patients	To analyze in detail the decision-making process for AVR that follows the diagnosis of severe AS with Class I indications, in order to identify the barriers to surgery.	The mean aortic valve area was 0.72 +/- 0.19 cm2 and the left ventricular ejection fraction 54 +/- 21%. A Class I indication for AVR was present in 174 patients (93%), of whom 125 (72%) were referred for AVR, which was performed in 93 cases (53%). The reasons for no AVR (n=81) were patient refusal in 29 cases (36%), comorbidities in 28 (35%), while in 19 patients (23%) the AS was considered as 'not severe', despite being categorized as severe by ACC/AHA guidelines. The predominant factors in making the nonsurgical decision were the patient or family (36%), the cardiologist (33%), and the surgeon (21%).	4
8. Iung B, Baron G, Butchart EG, et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *Eur Heart J.* 2003;24(13):1231-1243.	Review/Other-Tx	5,001 patients	To identify the characteristics, treatment, and outcomes of contemporary patients with valvular heart disease in Europe, and to examine adherence to guidelines.	Valvular heart disease was native in 71.9% of patients and 28.1% had had a previous intervention. Mean age was 64 +/- 14 years. Degenerative etiologies were the most frequent in aortic valvular heart disease and mitral regurgitation while most cases of mitral stenosis were of rheumatic origin. Coronary angiography was used in 85.2% of patients before intervention. Of the 1,269 patients who underwent intervention, prosthetic replacement was performed in 99.0% of aortic valvular heart disease, percutaneous dilatation in 33.9% of mitral stenosis, and valve repair in 46.5% of mitral regurgitation; 31.7% of patients had ≥1 associated procedure. Of patients with severe, symptomatic, single valvular heart disease, 31.8% did not undergo intervention, most frequently because of comorbidities. In asymptomatic patients, accordance with guidelines ranged between 66.0% and 78.5%. Operative mortality was <5% for single valvular heart disease.	4

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
9. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med.* 2014;370(19):1790-1798.	Experimental-Tx	795 patients	To compare TAVR, using a self-expanding transcatheter aortic-valve bioprosthesis, with surgical aortic-valve replacement in patients with severe AS and an increased risk of death during surgery.	A total of 795 patients underwent randomization at 45 centers in the United States. In the as-treated analysis, the rate of death from any cause at 1 year was significantly lower in the TAVR group than in the surgical group (14.2% vs 19.1%), with an absolute reduction in risk of 4.9 percentage points (upper boundary of the 95% CI, -0.4; $P<0.001$ for noninferiority; $P=0.04$ for superiority). The results were similar in the intention-to-treat analysis. In a hierarchical testing procedure, TAVR was noninferior with respect to echocardiographic indexes of valve stenosis, functional status, and quality of life. Exploratory analyses suggested a reduction in the rate of major adverse cardiovascular and cerebrovascular events and no increase in the risk of stroke.	1

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EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
10. Buellesfeld L, Gerckens U, Schuler G, et al. 2-year follow-up of patients undergoing transcatheter aortic valve implantation using a self-expanding valve prosthesis. *J Am Coll Cardiol.* 2011;57(16):1650-1657.	Observational-Tx	126 patients	To evaluate the safety, device performance, and clinical outcome up to 2 years for patients undergoing TAVI.	In all, 126 patients (mean age 82 years, 42.9% male, mean logistic European System for Cardiac Operative Risk Evaluation score [EuroSCORE] 23.4%) with severe aortic valve stenosis (mean gradient 46.8 mm Hg) underwent the TAVI procedure. Access was transfemoral in all but 2 cases with subclavian access. Retrospective risk stratification classified 54 patients as moderate surgical risk, 51 patients as high-risk operable, and 21 patients as high-risk inoperable. The overall technical success rate was 83.1%. 30-day all-cause mortality was 15.2%, without significant differences in the subgroups. At 2 years, all-cause mortality was 38.1%, with a significant difference between the moderate-risk group and the combined high-risk groups (27.8% vs 45.8%, *P*=0.04). This difference was mainly attributable to an increased risk of noncardiac mortality among patients constituting the high-risk groups. Hemodynamic results remained unchanged during follow-up (mean gradient: 8.5 +/- 2.5 mm Hg at 30 days and 9.0 +/- 3.4 mm Hg at 2 years). Functional class improved in 80% of patients and remained stable over time. There was no incidence of structural valve deterioration.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
11. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med.* 2010;363(17):1597-1607.	Observational-Tx	358 patients	To report the outcomes with TAVI as compared with standard therapy among the patients in the PARTNER trial who were not suitable candidates for surgery.	A total of 358 patients with AS who were not considered to be suitable candidates for surgery underwent randomization at 21 centers (17 in the United States). At 1 year, the rate of death from any cause (Kaplan-Meier analysis) was 30.7% with TAVI, as compared with 50.7% with standard therapy (HR with TAVI, 0.55; 95% CI, 0.40 to 0.74; $P<0.001$). The rate of the composite end point of death from any cause or repeat hospitalization was 42.5% with TAVI as compared with 71.6% with standard therapy (HR, 0.46; 95% CI, 0.35 to 0.59; $P<0.001$). Among survivors at 1 year, the rate of cardiac symptoms (New York Heart Association class III or IV) was lower among patients who had undergone TAVI than among those who had received standard therapy (25.2% vs 58.0%, $P<0.001$). At 30 days, TAVI, as compared with standard therapy, was associated with a higher incidence of major strokes (5.0% vs 1.1%, $P=0.06$) and major vascular complications (16.2% vs 1.1%, $P<0.001$). In the year after TAVI, there was no deterioration in the functioning of the bioprosthetic valve, as assessed by evidence of stenosis or regurgitation on an echocardiogram.	2

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
12. Meredith Am IT, Walters DL, Dumonteil N, et al. Transcatheter aortic valve replacement for severe symptomatic aortic stenosis using a repositionable valve system: 30-day primary endpoint results from the REPRISE II study. *J Am Coll Cardiol.* 2014;64(13):1339-1348.	Observational-Tx	120 patients	To assess safety and performance of REpositionable Percutaneous Replacement of Stenotic Aortic Valve Through Implantation of Lotus Valve System (REPRISE II) in patients at high risk for surgical intervention.	Mean age was 84.4 years, 57% of the patients were female, and 76% were New York Heart Association functional class III/IV. Mean aortic valve area was 0.7 +/- 0.2 cm2. The valve was successfully implanted in all patients, with no cases of valve embolization, ectopic valve deployment, or additional valve implantation. All repositioning (n = 26) and retrieval (n = 6) attempts were successful; 34 patients (28.6%) received a permanent pacemaker. The primary device performance endpoint was met, because the mean gradient improved from 46.4 +/- 15.0 mm Hg to 11.5 +/- 5.2 mm Hg. At 30 days, the mortality rate was 4.2%, and the rate of disabling stroke was 1.7%; 1 (1.0%) patient had moderate paravalvular regurgitation, whereas none had severe paravalvular regurgitation.	2
13. Mohr FW, Holzhey D, Mollmann H, et al. The German Aortic Valve Registry: 1-year results from 13,680 patients with aortic valve disease. *Eur J Cardiothorac Surg.* 2014;46(5):808-816.	Review/Other-Tx	13,860 patients	To gather clinical information on all aortic valve procedures (transcutaneous and conventional, including patients being treated for coronary disease) currently being performed in Germany.	The 1-year mortality rate was 6.7% for conventional AVR patients (n = 6523) and 11.0% for patients who underwent AVR with coronary artery bypass grafting (n = 3464). The 1-year mortality rate was 20.7 and 28.0% in transvascular-/transapical-TAVR patients, respectively (n = 2695 and 1181). However, if patients were stratified into 4 risk groups by means of the EuroSCORE and the German AV Score, the highest risk cohorts showed the same mortality at 1 year with either therapy. More than 80% of patients in all groups were in the same or better state of health at 1 year post-intervention and were satisfied with the procedural outcome.	4

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
14. Schymik G, Lefevre T, Bartorelli AL, et al. European experience with the second-generation Edwards SAPIEN XT transcatheter heart valve in patients with severe aortic stenosis: 1-year outcomes from the SOURCE XT Registry. *JACC Cardiovasc Interv.* 2015;8(5):657-669.	Review/Other-Tx	2,688 patients	To describe the baseline risk factors in the patient population undergoing TAVR with the balloon-expandable valve and the clinical outcomes at 30 days and 1 year after implantation of the SAPIEN XT valve in a real-world setting.	The mean age was 81.4 +/- 6.6 years, 42.3% were male, and the mean logistic EuroSCORE was 20.4 +/- 12.4%. Patients had a high burden of coronary disease (44.2%), diabetes (29.4%), renal insufficiency (28.9%), atrial fibrillation (25.6%), and peripheral vascular disease (21.2%). Survival was 93.7% at 30 days and 80.6% at 1 year. At 30-day follow-up, the stroke rate was 3.6%, the rate of major vascular complications was 6.5%, the rate of life-threatening bleeding was 5.5%, the rate of new pacemakers was 9.5%, and the rate of moderate/severe paravalvular leak was 5.5%. Multivariable analysis identified nontransfemoral approach (HR: 1.84; $P<0.0001$), renal insufficiency (HR: 1.53; $P<0.0001$), liver disease (HR: 1.67; $P=0.0453$), moderate/severe tricuspid regurgitation (HR: 1.47; $P=0.0019$), porcelain aorta (HR: 1.47; $P=0.0352$), and atrial fibrillation (HR: 1.41; $P=0.0014$), with the highest HRs for 1-year mortality. Major vascular complications and major/life-threatening bleeding were the most frequently seen complications associated with a significant increase in 1-year mortality.	4

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
15. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med.* 2011;364(23):2187-2198.	Experimental-Tx	699 patients	To describe the results for the high-risk subgroup of patients in the PARTNER trial who were still candidates for surgical valve replacement and who were randomly assigned to undergo either transcatheter or surgical replacement of the aortic valve.	The rates of death from any cause were 3.4% in the transcatheter group and 6.5% in the surgical group at 30 days (P=0.07) and 24.2% and 26.8%, respectively, at 1 year (P=0.44), a reduction of 2.6 percentage points in the transcatheter group (upper limit of the 95% CI, 3.0 percentage points; predefined margin, 7.5 percentage points; P=0.001 for noninferiority). The rates of major stroke were 3.8% in the transcatheter group and 2.1% in the surgical group at 30 days (P=0.20) and 5.1% and 2.4%, respectively, at 1 year (P=0.07). At 30 days, major vascular complications were significantly more frequent with transcatheter replacement (11.0% vs 3.2%, P<0.001); adverse events that were more frequent after surgical replacement included major bleeding (9.3% vs 19.5%, P<0.001) and new-onset atrial fibrillation (8.6% vs 16.0%, P=0.006). More patients undergoing transcatheter replacement had an improvement in symptoms at 30 days, but by 1 year, there was not a significant between-group difference.	1

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
16. Thomas M, Schymik G, Walther T, et al. One-year outcomes of cohort 1 in the Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) registry: the European registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve. *Circulation.* 2011;124(4):425-433.	Observational-Tx	463 transfemoral patients and 575 transapical patients	To present the outcomes of the Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry which was designed to assess initial post commercial clinical TAVI results of the Edwards SAPIEN valve in consecutive patients in Europe.	Cohort 1 consists of 1,038 patients enrolled at 32 centers. 1-year outcomes are presented. Patients with the transapical approach (n=575) suffered more comorbidities than transfemoral patients (n=463) with a significantly higher logistic EuroSCORE (29% vs 25.8%; *P*=0.007). These groups are different; therefore, outcomes cannot be directly compared. Total Kaplan Meier 1-year survival was 76.1% overall, 72.1% for transapical and 81.1% for transfemoral patients, and 73.5% of surviving patients were in New York Heart Association (NYHA) class I or II at 1 year. Combined transapical and transfemoral causes of death were cardiac in 25.1%, noncardiac in 49.2%, and unknown in 25.7%. Pulmonary complications (23.9%), renal failure (12.5%), cancer (11.4%), and stroke (10.2%) were the most frequent noncardiac causes of death. Multivariable analysis identified logistic EuroSCORE, renal disease, liver disease, and smoking as variables with the highest HRs for 1-year mortality whereas carotid artery stenosis, hyperlipidemia, and hypertension were associated with lower mortality.	2
17. Webb J, Gerosa G, Lefevre T, et al. Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve. *J Am Coll Cardiol.* 2014;64(21):2235-2243.	Observational-Tx	150	To evaluate whether TAVR with this third-generation valve would be a viable alternative to high- or intermediate-risk surgery for severe AS.	Patients were 83.6 +/- 5.0 years of age, with multiple comorbidities reflected by a Society of Thoracic Surgeons score of 7.4 +/- 4.5% and logistic EuroSCORE of 21.6 +/- 12.3%. A transfemoral approach was chosen in 64.0% and alternative access (transapical/direct aortic) in the remainder. At 30 days, paravalvular regurgitation was none to mild in 96.4% and moderate in 3.5%. No patient had severe regurgitation. Transfemoral implantation was associated with low mortality (2.1%), no disabling stroke (0.0%), and fully percutaneous access and closure in 95.8%. Nontransfemoral alternative access was associated with higher rates of mortality (11.6%) and stroke (5.6%).	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
18. Zahn R, Gerckens U, Grube E, et al. Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. *Eur Heart J.* 2011;32(2):198-204.	Observational-Tx	697 patients	To evaluate indications, interventions, and clinical outcome as well as quality of life measurements of the TAVI procedure in routine clinical practice.	Between January 2009 and December 2009, a total of 697 patients (81.4 +/- 6.3 years, 44.2% males, and logistic EuroScore 20.5 +/- 13.2%) underwent TAVI. Preoperative aortic valve area was 0.6 +/- 0.2 cm(2) with a mean transvalvular gradient of 48.7 +/- 17.2 mmHg. TAVI was performed percutaneously in the majority of patients [666 (95.6%)]. Only 31 (4.4%) procedures were done surgically: 26 (3.7%) transapically and 5 (0.7%) transaortically. The Medtronic CoreValve prosthesis was used in 84.4%, whereas the Sapien Edwards prosthesis was used in the remaining cases. Technical success was achieved in 98.4% with a post-operative mean transaortic pressure gradient of 5.4 +/- 6.2 mmHg. Any residual aortic regurgitation was observed in 72.4% of patients, with a significant aortic insufficiency (≥Grade III) in only 16 patients (2.3%). Complications included pericardial tamponade in 1.8% and stroke in 2.8% of patients. Permanent pacemaker implantation after TAVI became necessary in 39.3% of patients. In-hospital death rate was 8.2% and the 30-day death rate 12.4%.	1
19. Achenbach S, Delgado V, Hausleiter J, Schoenhagen P, Min JK, Leipsic JA. SCCT expert consensus document on computed tomography imaging before transcatheter aortic valve implantation (TAVI)/transcatheter aortic valve replacement (TAVR). *J Cardiovasc Comput Tomogr.* 2012;6(6):366-380.	Review/Other-Dx	N/A	This consensus document provides recommendations about the use of CT imaging in patients scheduled for TAVR/TAVI, including data acquisition, interpretation, and reporting.	CT imaging plays an important role in procedural planning for TAVI/TAVR and should be a fully integrated component of any TAVI/TAVR program. The use of CT in TAVI/TAVR is multifaceted and should include the assessment of vascular access of the aortic valve, annulus, and root and of the orientation of the annulus plane. Importantly, the person responsible for the interpretation of the CT examination should be integrated in the TAVI/TAVR team to ensure appropriate incorporation into the patient selection process and procedure planning.	4

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
20. Barbanti M, Yang TH, Rodes Cabau J, et al. Anatomical and procedural features associated with aortic root rupture during balloon-expandable transcatheter aortic valve replacement. *Circulation.* 2013;128(3):244-253.	Observational-Dx	31 patients	To identify predictors of aortic root rupture during balloon-expandable TAVR by using MDCT.	There were no significant differences between the 2 groups in any preoperative clinical and echocardiographic variables. Aortic root rupture was identified in 20 patients and periaortic hematoma in 11. Patients with root rupture had a higher degree of subannular/left ventricular outflow tract calcification quantified by the Agatston score (181.2±211.0 vs 22.5±37.6, $P<0.001$), and a higher frequency of ≥20% annular area oversizing (79.4% vs 29.0%, $P<0.001$) and balloon postdilatation (22.6% vs 0.0%, $P=0.005$). In conditional logistic regression analysis for the matched data, moderate/severe left ventricular outflow tract/subannular calcifications (OR, 10.92; 95% CI, 3.23–36.91; $P<0.001$) and prosthesis oversizing ≥20% (OR, 8.38; 95% CI, 2.67–26.33; $P<0.001$) were associated with aortic root contained/noncontained rupture.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
21. Binder RK, Leipsic J, Wood D, et al. Prediction of optimal deployment projection for transcatheter aortic valve replacement: angiographic 3-dimensional reconstruction of the aortic root versus multidetector computed tomography. *Circ Cardiovasc Interv.* 2012;5(2):247-252.	Observational-Dx	40 patients	To evaluate the ability and practicability of 3D angiographic reconstructions to find the optimal perpendicular valve projection for accurate positioning and deployment of valve prosthesis in TAVR and compared this method with MDCT.	Patients underwent preimplant 3D angiographic reconstructions and 68% underwent preimplant MDCT. 3D angiographic reconstructions were generated from images of a C-arm rotational aortic root angiogram during breath-hold, rapid ventricular pacing, and injection of 32 mL contrast medium at 8 mL/s. 2 independent operators prospectively predicted perpendicular valve projections. The implant angle was chosen at the discretion of the physician performing TAVR. The angles from 3D angiographic reconstructions, from MDCT, the implant angle, and the postdeployment perpendicular prosthesis view were compared. The shortest distance from the postdeployment perpendicular prosthesis projection to the regression line of predicted perpendicular projections was calculated. All but 1 patient had adequate image quality for reproducible angle predictions. There was a significant correlation between 3D angiographic reconstructions and MDCT for prediction of perpendicular valve projections (r=0.682, $P<0.001$). Deviation from the regression line of predicted angles to the postdeployment prosthesis view was 5.1+/-4.6 degrees for 3D angiographic reconstructions and 7.9+/-4.9 degrees for MDCT ($P=0.01$).	2
22. Binder RK, Webb JG, Willson AB, et al. The impact of integration of a multidetector computed tomography annulus area sizing algorithm on outcomes of transcatheter aortic valve replacement: a prospective, multicenter, controlled trial. *J Am Coll Cardiol.* 2013;62(5):431-438.	Observational-Dx	266 patients	To investigate the impact of integration of a MDCT annular area sizing algorithm on TAVR outcomes.	Of 266 patients, 133 consecutive patients underwent TAVR (SAPIEN XT THV) in the MDCT group and 133 consecutive patients were in the control group. More than mild paravalvular regurgitation was present in 5.3% (7 of 133) of the MDCT group and in 12.8% (17 of 133) in the control group ($P=0.032$). The combined secondary endpoint occurred in 3.8% (5 of 133) of the MDCT group and in 11.3% (15 of 133) of the control group ($P=0.02$), driven by the difference of severe paravalvular regurgitation.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
23. Bloomfield GS, Gillam LD, Hahn RT, et al. A practical guide to multimodality imaging of transcatheter aortic valve replacement. *JACC Cardiovasc Imaging.* 2012;5(4):441-455.	Review/Other-Dx	N/A	To address the requirements for and utility of multimodality imaging in the continuum of TAVR patient care.	No results stated in abstract.	4
24. Gurvitch R, Wood DA, Leipsic J, et al. Multislice computed tomography for prediction of optimal angiographic deployment projections during transcatheter aortic valve implantation. *JACC Cardiovasc Interv.* 2010;3(11):1157-1165.	Observational-Dx	20 patients	To describe a novel method of predicting optimal angiographic deployment projections for TAVI and assess whether such predictions may result in improved valve positioning and outcomes.	Correct final deployment projections were more frequent in the MSCT-guided compared with non-MSCT-guided group: excellent or satisfactory projections (90% vs 65%, P=0.06). The MSCT angle prediction was accurate but dependent on optimal images (optimal images: 93% of predicted angles were excellent or satisfactory, suboptimal images: 73% of predicted angles were poor). A "line of perpendicularity" could be generated with optimal projections across the right-to-left anterior oblique plane by adding the correct cranial or caudal angulation.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
25. Hayashida K, Lefevre T, Chevalier B, et al. Transfemoral aortic valve implantation new criteria to predict vascular complications. *JACC Cardiovasc Interv.* 2011;4(8):851-858.	Observational-Dx	130 patients	To evaluate the incidence, impact, and predictors of vascular complications in TAVI.	In our cohort of elderly patients (83.3 +/- 5.9 years), the logistic EuroScore was 25.8% +/- 11.9%. The Edwards valve was used in 102 cases (18- to 24-F) and the CoreValve in 27 (18-F). The minimal femoral artery diameter was 8.17 +/- 1.14 mm, and the calcification (0 to 3) and tortuosity scores (0 to 3) were 0.58 +/- 0.72 and 0.28 +/- 0.53, respectively. The mean sheath diameter was 8.10 +/- 0.82 mm, and the mean sheath to femoral artery ratio was 0.99 +/- 0.16. Vascular complications occurred in 27.6% (VARC [Valve Academic Research Consortium] major: 17.3%, minor: 10.2%), and major vascular complications predicted 30-day mortality (22.7% vs 7.6%, *P*=0.049). The sheath to femoral artery ratio (HR: 186.20, 95% CI: 4.41 to 7,855.11), center experience (HR: 3.66, 95% CI: 1.17 to 11.49), and femoral calcification (HR: 3.44, 95% CI: 1.16 to 10.17) predicted major complications by multivariate analysis. An sheath to femoral artery ratio threshold of 1.05 (AUC = 0.727) predicted a higher rate of VARC major complications (30.9% vs 6.9%, *P*=0.001) and 30-day mortality (18.2% vs 4.2%, *P*=0.016).	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
26. Kodali SK, Williams MR, Smith CR, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. *N Engl J Med.* 2012;366(18):1686-1695.	Observational-Tx	699 patients	To describe the 2-year (and longer) clinical outcomes and echocardiographic findings after TAVR or surgical aortic-valve replacement in the high-risk patients in the PARTNER trial who could undergo surgery.	The rates of death from any cause were similar in the TAVR and surgery groups (HR with TAVR, 0.90; 95% CI, 0.71 to 1.15; *P*=0.41) and at 2 years (Kaplan-Meier analysis) were 33.9% in the TAVR group and 35.0% in the surgery group (*P*=0.78). The frequency of all strokes during follow-up did not differ significantly between the 2 groups (HR, 1.22; 95% CI, 0.67 to 2.23; *P*=0.52). At 30 days, strokes were more frequent with TAVR than with surgical replacement (4.6% vs 2.4%, *P*=0.12); subsequently, there were 8 additional strokes in the TAVR group and 12 in the surgery group. Improvement in valve areas was similar with TAVR and surgical replacement and was maintained for 2 years. Paravalvular regurgitation was more frequent after TAVR (*P*<0.001), and even mild paravalvular regurgitation was associated with increased late mortality (*P*<0.001).	1
27. Kurra V, Kapadia SR, Tuzcu EM, et al. Pre-procedural imaging of aortic root orientation and dimensions: comparison between X-ray angiographic planar imaging and 3-dimensional multidetector row computed tomography. *JACC Cardiovasc Interv.* 2010;3(1):105-113.	Observational-Dx	40 patients	To examine whether contrast-enhanced MDCT allows prediction of X-ray angiographic planes for the root angiogram in the context of TAVI.	The cranial angulation in the left anterior oblique X-ray angiograms (mean left anterior oblique: 39+/- 8, n=38) and matched MDCT images were not significantly different (cranial: 25 +/- 7 vs 23 +/- 8; *P*=0.214). There was a small but significant difference between the caudal angulation in the right anterior oblique angiogram (mean right anterior oblique: 25 +/- 5, n=40) and matched CT images (caudal: 21 +/- 9 vs 29 +/- 10; *P*=0.002). The annulus diameter in the left anterior oblique projection was not significantly different between X-ray angiography and contrast-enhanced MDCT (2.3 +/- 0.3 vs 2.4 +/- 0.3; *P*=0.052), whereas there was a small but significant difference in the annulus diameter in right anterior oblique projections between angiography and MDCT (2.4 +/- 0.3 vs 2.2 +/- 0.3; *P*=0.029).	2
28. Mack MJ. Access for transcatheter aortic valve replacement: which is the preferred route? *JACC Cardiovasc Interv.* 2012;5(5):487-488.	Review/Other-Tx	N/A	Commentary on method of delivery access for TAVR.	No results stated in abstract.	4

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
29. Mylotte D, Dorfmeister M, Elhmidi Y, et al. Erroneous measurement of the aortic annular diameter using 2-dimensional echocardiography resulting in inappropriate CoreValve size selection: a retrospective comparison with multislice computed tomography. *JACC Cardiovasc Interv.* 2014;7(6):652-661.	Observational-Dx	157 patients	To assess the differential adherence to THV-oversizing principles between TEE and MSCT and its impact on the incidence of paravalvular leak.	Using TEE-derived annulus measurements, 157 patients underwent CoreValve implantation (23 mm: n = 66; 29 mm: n = 91). The estimated THV oversizing on the basis of TEE was 20.1 +/- 8.2%. Retrospective CT analysis yielded larger annular diameters than TEE (P<0.0001). When these CT diameters were used to recalculate the percentage of oversizing achieved with the TEE-selected CoreValve, the actual THV oversizing was only 10.4 +/- 7.8%. Consequently, CT analysis suggested that up to 50% of patients received an inappropriate CoreValve size. When CT-based sizing criteria were satisfied, the incidence of paravalvular leak was 21% lower than that with echocardiography (14% vs 35%; P=0.003). Adherence to CT-based oversizing was independently associated with a reduced incidence of paravalvular leak (OR 0.36; 95% CI: 0.14 to 0.90; P=0.029); adherence to TEE-based sizing was not.	3
30. Okuyama K, Jilaihawi H, Kashif M, et al. Transfemoral access assessment for transcatheter aortic valve replacement: evidence-based application of computed tomography over invasive angiography. *Circ Cardiovasc Imaging.* 2015;8(1).	Observational-Dx	496 transfemoral cases	To compare the predictive value of vascular CT and angiography for vascular complications, to identify the optimal imaging strategy to best predict vascular complications, and thereby streamline and provide a clear evidence base for practice.	In patients undergoing both contrast CT and angiography (n=283; 35 sheath-related complications), contrast CT showed a greater predictive value than angiography by AUC P<0.001): 0.87 (95% CI: 0.82–0.91) vs 0.72 (95% CI: 0.66–0.77). In patients undergoing both noncontrast CT and angiography (n=103; 17 sheath-related complications), there was no difference between noncontrast CT and angiography: 0.79 (95% CI: 0.70–0.86) vs 0.73 (95% CI: 0.63–0.81). 3D assessments of calcification and tortuosity provided limited additional value for sheath-related complication prediction.	3

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
31. Ribeiro HB, Webb JG, Makkar RR, et al. Predictive factors, management, and clinical outcomes of coronary obstruction following transcatheter aortic valve implantation: insights from a large multicenter registry. *J Am Coll Cardiol.* 2013;62(17):1552-1562.	Observational-Dx	44 patients	To evaluate the main baseline and procedural characteristics, management, and clinical outcomes of patients from a large cohort of patients undergoing TAVI who suffered coronary obstruction.	Baseline and procedural variables associated with coronary obstruction were older age (P<0.001), female sex (P<0.001), no previous coronary artery bypass graft (P=0.043), the use of a balloon-expandable valve (P=0.023), and previous surgical aortic bioprosthesis (P=0.045). The left coronary artery was the most commonly involved (88.6%). The mean left coronary artery ostia height and sinus of Valsalva diameters were lower in patients with obstruction than in control subjects (10.6 +/- 2.1 mm vs 13.4 +/- 2.1 mm, P<0.001; 28.1 +/- 3.8 mm vs 31.9 +/- 4.1 mm, P<0.001). Differences between groups remained significant after the case-matched analysis (P<0.001 for coronary height; P=0.01 for sinus of Valsalva diameter). Most patients presented with persistent severe hypotension (68.2%) and electrocardiographic changes (56.8%). Percutaneous coronary intervention was attempted in 75% of the cases and was successful in 81.8%. 30-day mortality was 40.9%. After a median follow-up of 12 (2 to 18) months, the cumulative mortality rate was 45.5%, and there were no cases of stent thrombosis or reintervention.	3

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
32. Toggweiler S, Gurvitch R, Leipsic J, et al. Percutaneous aortic valve replacement: vascular outcomes with a fully percutaneous procedure. *J Am Coll Cardiol.* 2012;59(2):113-118.	Observational-Dx	137 patients	To evaluate vascular complications in a consecutive patient population undergoing transfemoral percutaneous aortic valve replacement using current VARC definitions.	Percutaneous aortic valve replacement was performed in 137 consecutive patients. All but 1 patient underwent planned arteriotomy closure using a percutaneous pre-closure technique. Smaller sheaths, rigorous angiographic and CT screening and patient selection, and percutaneous vascular repair techniques were increasingly used over this period. From 2009 to 2010, major vascular complications decreased from 8% to 1% (P=0.06), minor vascular complications decreased from 24% to 8% (P<0.01), major bleeds fell from 14% to 1% (P<0.01), and unplanned surgery decreased from 28% to 2% (P<0.01). A minimal artery diameter smaller than the external sheath diameter, moderate or severe calcification, and peripheral vascular disease were associated with higher vascular complication rates.	2
33. Khalique OK, Hahn RT, Gada H, et al. Quantity and location of aortic valve complex calcification predicts severity and location of paravalvular regurgitation and frequency of post-dilation after balloon-expandable transcatheter aortic valve replacement. *JACC Cardiovasc Interv.* 2014;7(8):885-894.	Observational-Dx	150 patients	To determine the impact of quantity and location of aortic valve calcification on paravalvular regurgitation and rates of post-dilation immediately after TAVR.	Quantity of and asymmetry of aortic valve calcification for all regions of the aortic valve complex predicted greater than or equal to mild paravalvular regurgitation by receiver-operating characteristic analysis (AUC = 0.635 to 0.689), except Leaflet asymmetry. Receiver-operating characteristic analysis for post-dilation was significant for quantity and asymmetry of aortic valve calcification in all regions, with higher AUC values than for paravalvular regurgitation (AUC = 0.648 to 0.741). On multivariable analysis, Leaflet and AnnulusLVOT calcification were independent predictors of both paravalvular regurgitation and post-dilation regardless of multidetector row computed tomography area cover index.	3
34. American College of Radiology. ACR–NASCI–SIR–SPR Practice Parameter for the Performance and Interpretation of Body Computed Tomography Angiography (CTA). Available at: http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Body_CTA.pdf.	Review/Other-Dx	N/A	Guidance document to promote the safe and effective use of diagnostic and therapeutic radiology by describing specific training, skills and techniques.	N/A	4

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
35. Khalique OK, Kodali SK, Paradis JM, et al. Aortic annular sizing using a novel 3-dimensional echocardiographic method: use and comparison with cardiac computed tomography. *Circ Cardiovasc Imaging.* 2014;7(1):155-163.	Observational-Dx	100 patients	To compare annulus measurements from 3D-TEE using off-label use of commercially available software with MDCT measurements and assesses their ability to predict paravalvular regurgitation.	3D-TEE and MDCT cross-sectional perimeter and area measurements were strongly correlated (r=0.93-0.94; *P*<0.0001); however, the small differences (≤1%) were statistically significant (*P*=0.0002 and 0.0074, respectively). Discriminatory ability for ≥ mild paravalvular regurgitation was good for both MDCT (AUC for perimeter and area cover index=0.715 and 0.709, respectively) and 3D-TEE (AUC for perimeter and area cover index=0.709 and 0.694, respectively). Differences in receiver operating characteristic analysis between MDCT and 3D-TEE perimeter and area cover indexes were not statistically significant (*P*=0.15 and 0.35, respectively).	2
36. Zamorano JL, Badano LP, Bruce C, et al. EAE/ASE recommendations for the use of echocardiography in new transcatheter interventions for valvular heart disease. *Eur Heart J.* 2011;32(17):2189-2214.	Review/Other-Dx	N/A	To develop recommendations for the use of echocardiography in new transcatheter interventions for valvular heart disease.	No results stated in abstract.	4
37. Koos R, Altiok E, Mahnken AH, et al. Evaluation of aortic root for definition of prosthesis size by magnetic resonance imaging and cardiac computed tomography: implications for transcatheter aortic valve implantation. *Int J Cardiol.* 2012;158(3):353-358.	Observational-Dx	58 patients	To compare CMR with dual source CT for analysis of aortic root dimensions prior to TAVI.	CMR and dual source CT aortic root measurements showed an overall good correlation (r=0.86, *P*<0.001 for coronal aortic annulus diameters). There was also a good correlation between TEE and CMR as well as between TEE and dual source CT for measurement of sagittal aortic annulus diameters (r=0.69, *P*<0.001). However, annulus diameters assessed by TEE (22.1+/-2.3mm) were significantly smaller than coronal aortic annulus diameters assessed by CMR (23.4+/-1.8mm, *P*<0.001) or dual source CT (23.6+/-1.8, *P*<0.001). Regarding TAVI strategy, the agreement between TEE and sagittal CMR (kappa=0.89) as well as sagittal dual source CT measurements (kappa=0.87) was statistically perfect. However, decision based on coronal CMR- or MSCT measurements would have modified TAVI strategy as compared to a TEE based choice in a significant number of patients (22% to 24%).	3

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
38. Pontone G, Andreini D, Bartorelli AL, et al. Comparison of accuracy of aortic root annulus assessment with cardiac magnetic resonance versus echocardiography and multidetector computed tomography in patients referred for transcatheter aortic valve implantation. *Am J Cardiol.* 2013;112(11):1790-1799.	Observational-Dx	80 patients	To compare the accuracy of CMR evaluation of the aortic annulus with TTE and TEE and MDCT in patients referred for TAVI.	In 50 patients, maximum diameter, minimum diameter and aortic annulus, length of the left coronary, right coronary, and noncoronary aortic leaflets, degree (grades 1 to 4) of aortic leaflet calcification, and distance between aortic annulus and coronary artery ostia were assessed. Aortic annulus maximum diameter, minimum diameter, and area by CMR were 26.4 +/- 2.8 mm, 20.6 +/- 2.3 mm, 449.8 +/- 86.2 mm(2), respectively. The length of left coronary, right coronary, and noncoronary leaflets by CMR were 13.9 +/- 2.2, 13.3 +/- 2.1, and 13.4 +/- 1.8 mm, respectively, whereas the score of aortic leaflet calcifications was 2.9 +/- 0.8. Finally, the distances between aortic annulus and left main and right coronary artery ostia were 16.1 +/- 2.8 and 16.1 +/- 4.4 mm, respectively. Regarding aortic annulus area, TTE and TEE showed an underestimation (P<0.01), with a moderate agreement (r: 0.5 and 0.6, respectively, P<0.01) compared with CMR.	2

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
39. Ruile P, Blanke P, Krauss T, et al. Pre-procedural assessment of aortic annulus dimensions for transcatheter aortic valve replacement: comparison of a non-contrast 3D MRA protocol with contrast-enhanced cardiac dual-source CT angiography. *Eur Heart J Cardiovasc Imaging.* 2016;17(4):458-466.	Observational-Dx	104 patients	To evaluate the feasibility of a noncontrast 3D-FLASH MRA protocol for preprocedural aortic annulus assessment for TAVR in comparison with cardiac dual-source CTA.	In this prospective study, 69 of 104 consecutive patients (mean age 81.8 +/- 5.4 years, 37.7% arrhythmic) with severe AS who had undergone pre-TAVR cardiac CTA received a respiratory and ECG-triggered, noncontrast 3D-FLASH MRA at 3 T. Annular area measurements were obtained at mid-diastole for both modalities whereas maximum systolic area was assessed by CTA only. Systolic MRA dimensions were modelled, by adding the relative difference of systolic and diastolic CTA area dimensions as a corrective factor. Hypothetical prosthesis sizing was performed based on systolic CTA, diastolic, and modelled systolic MRA area measurements. MRI quality and degree of annular calcifications were evaluated using 4-point-grading scales. The mean acquisition time was 14 +/- 4.2 min. The mean image quality was 3.1 +/- 0.9 with only 2 examinations rated nondiagnostic. The mean degree of calcifications was equal. As assessed by Bland-Altman analysis, there was no relevant systematic difference between area measurements for modelled systolic MRA and systolic CTA [the mean difference -3.1 mm(2) (limits of agreement -44.4 mm(2); 38.2 mm(2))]. Agreement for hypothetical prosthesis sizing was found in 63 of 67 (94%) patients for systolic CTA and modelled systolic MRA.	1

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
40. La Manna A, Sanfilippo A, Capodanno D, et al. Cardiovascular magnetic resonance for the assessment of patients undergoing transcatheter aortic valve implantation: a pilot study. *J Cardiovasc Magn Reson.* 2011;13:82.	Observational-Dx	49 patients	To compare CMR and TTE for the assessment of aortic valve measurements and left ventricular function in high-risk elderly patients submitted to TAVI.	Patients who underwent both TTE and CMR (n=49) had a mean age of 80.8 +/- 4.8 years and a mean logistic EuroSCORE of 14.9 +/- 9.3%. There was a good correlation between TTE and CMR in terms of annulus size (R2 = 0.48, *P*<0.001), left ventricular outflow tract diameter (R2 = 0.62, *P*<0.001) and left ventricular ejection fraction (R2 = 0.47, *P*<0.001) and a moderate correlation in terms of aortic valve area (R2 = 0.24, *P*<0.001). CMR generally tended to report larger values than TTE for all measurements. The Bland-Altman test indicated that the 95% limits of agreement between TTE and CMR ranged from -5.6 mm to + 1.0 mm for annulus size, from -0.45 mm to + 0.25 mm for left ventricular outflow tract, from -0.45 mm2 to + 0.25 mm2 for aortic valve area and from -29.2% to 13.2% for left ventricular ejection fraction.	2
41. Paelinck BP, Van Herck PL, Rodrigus I, et al. Comparison of magnetic resonance imaging of aortic valve stenosis and aortic root to multimodality imaging for selection of transcatheter aortic valve implantation candidates. *Am J Cardiol.* 2011;108(1):92-98.	Observational-Dx	24 patients	To compare the aortic valve area, aortic valve annulus, and aortic root dimensions measured using MRI with catheterization, TTE, and TEE.	In 24 consecutive, high-risk, symptomatic patients with severe AS, aortic valve area was prospectively determined using MRI and direct planimetry using 3D TTE and calculated by catheterization using the Gorlin equation and by Doppler echocardiography using the continuity equation. Aortic valve annulus and the aortic root dimensions were prospectively measured using MRI, 2D TTE, and invasive aortography. In addition, aortic valve annulus was measured using TEE. No differences in aortic valve area were found among MRI, Doppler echocardiography, and 3D TTE compared with catheterization (*P*=NS). Invasive angiography underestimated aortic valve annulus compared with MRI (*P*<0.001), TEE (*P*<0.001), and 2D TTE (*P*<0.001). 2D TTE tended to underestimate the aortic valve annulus diameters compared to TEE and MRI. In contrast to 2D TTE, 3 patients had aortic valve annulus beyond the TAVI range using TEE and MRI.	1

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
42. Quail MA, Nordmeyer J, Schievano S, Reinthaler M, Mullen MJ, Taylor AM. Use of cardiovascular magnetic resonance imaging for TAVR assessment in patients with bioprosthetic aortic valves: comparison with computed tomography. *Eur J Radiol.* 2012;81(12):3912-3917.	Observational-Dx	21 patients	To compare CT and CMR for the evaluation of TAVR in a small cohort of patients with existing aortic bioprostheses.	16/21 patients had aortic bioprostheses constructed with a metal ring, and 5/21 patients had a metal strut construction. Patients with metal struts had significant metal-artifact on CMR, which compromised image quality in this region. There was good agreement between CT and CMR measurements of aortic geometry. The mean difference (d) in annulus area-derived diameter was 0.5mm (95% limits of agreement 4.2mm). There was good agreement between modalities for the cross-sectional area of the sinuses of valsalva (d 0.5 cm(2), limits of agreement 1.4 cm(2)), sinotubular junction (d 0.9 cm(2), limits of agreement 1.5 cm(2)), and ascending aorta (d 0.6 cm(2), limits of agreement 1.4 cm(2)). In patients without metal struts, the left coronary artery height d was 0.7 mm and limits of agreement 2.8mm.	2
43. Meyhoer J, Ahrens J, Neuss M, Holschermann F, Schau T, Butter C. Rotational angiography for preinterventional imaging in transcatheter aortic valve implantation. *Catheter Cardiovasc Interv.* 2012;79(5):756-765.	Observational-Dx	99 patients	To evaluate the clinical value of 3D rotational angiography, as a tool for imaging and measuring 3D anatomy, coupled with TEE as preinterventional imaging for TAVI procedures.	In all 99 patients, 3D rotational angiography was performed successfully with good imaging of the aortic root and measurements of the aortic annulus. In patients scheduled for SAPIEN valve implantation, the distances from the annulus to the coronary ostia were also measured. Of 99 patients, 80 subsequently underwent successful implantation. There is a good correlation to the TEE in the measured aortic annulus (22.13 +/- 2.09 mm in rotational angio, 21.58 +/- 2.09 mm TEE, Spearman r = 0.88, 95% IC [0.83;0.92], $P<0.0001$) and sinotubular junction (26.19 +/- 2.71 mm in rotational angio, 26.22 +/- 2.73 mm TEE, Spearman r = 0.83, 95% IC [0.75;0.88], $P<0.0001$). The effective dose is a fraction of the X-ray dose required for MSCT.	2

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
44. Greenbaum AB, O'Neill WW, Paone G, et al. Caval-aortic access to allow transcatheter aortic valve replacement in otherwise ineligible patients: initial human experience. *J Am Coll Cardiol.* 2014;63(25 Pt A):2795-2804.	Review/Other-Tx	19 patients	To describe the first use of caval-aortic access and closure to enable TAVR in patients who lacked other access options. Caval-aortic access refers to percutaneous entry into the abdominal aorta from the femoral vein through the adjoining inferior vena cava.	Between July 2013 and January 2014, 19 patients underwent TAVR via caval-aortic access; 79% were women. Caval-aortic access and tract closure were successful in all 19 patients; TAVR was successful in 17 patients. 6 patients experienced modified VARC-2 major vascular complications, 2 (11%) of whom required intervention. Most (79%) required blood transfusion. There were no deaths attributable to caval-aortic access. Throughout the 111 (range 39 to 229) days of follow-up, there were no post-discharge complications related to tract creation or closure. All patients had persistent aorto-caval flow immediately post-procedure. Of the 16 patients who underwent repeat imaging after the first week, 15 (94%) had complete closure of the residual aorto-caval tract.	4

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
45. Slovut DP, Ofstein LC, Bacharach JM. Endoluminal AAA repair using intravascular ultrasound for graft planning and deployment: a 2-year community-based experience. *J Endovasc Ther.* 2003;10(3):463-475.	Observational-Dx	173 patients	To examine the effectiveness of intravascular US and digital subtraction angiography for preoperative planning and intraoperative deployment of stent-grafts to treat abdominal aortic aneurysms.	Reliable preoperative intravascular US measurements were obtained in all patients. Plaque morphology was assessed in 140 (82.3%) aortic necks; in 36 (25.7%), preoperative intravascular US showed high-grade atherosclerotic plaque in the nonaneurysmal abdominal aortic neck. The procedure was successful in 168 (98.8%) cases (1 [0.6%] acute conversion and 1 access failure). There were 2 (1.2%) periprocedural deaths related to bowel ischemia. 4 (2.3%) patients developed graft occlusion/kinking and 2 (1.2%) developed renal failure requiring dialysis within 30 days. Multivariate logistic regression analysis revealed that female gender (P=0.0247), a short nonaneurysmal aortic neck (P=0.0185), and presence of high-grade atherosclerotic plaque (P=0.0185) correlated with major acute complications. Over a mean 10.4-month follow-up (range 1-25), 11 patients died of unrelated causes; there was no known AAA rupture or device failure. The Kaplan-Meier estimate of survival at 1 year was 91.0%+/-2.8%. 16 (9.4%) patients underwent 17 secondary procedures for endoleak or graft limb occlusion at a mean 5.4 months after stent-graft repair (freedom from secondary intervention at 1 year 86.5%+/-3.2%).	3

Imaging for Transcatheter Aortic Valve Replacement
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
46. Troianos CA, Hartman GS, Glas KE, et al. Guidelines for performing ultrasound guided vascular cannulation: recommendations of the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists. *J Am Soc Echocardiogr.* 2011;24(12):1291-1318.	Review/Other-Dx	N/A	To provide comprehensive practice guidelines on the use of US for vascular cannulation.	The recommendation is that on the basis of level 1 scientific evidence, properly trained clinicians use real-time US during internal jugular cannulation whenever possible to improve cannulation success and reduce the incidence of complications associated with the insertion of large-bore catheters. The use of real-time US for the cannulation of the internal jugular and femoral vein in pediatric patients is also recommended. Complications during femoral vein cannulation in adults are less severe than those that occur with subclavian and internal jugular vein cannulation, and therefore, US guidance is recommended only for identifying vessel overlap and patency when feasible for femoral vein cannulation.	4
47. White RA, Donayre C, Kopchok G, Walot I, Wilson E, de Virgilio C. Intravascular ultrasound: the ultimate tool for abdominal aortic aneurysm assessment and endovascular graft delivery. *J Endovasc Surg.* 1997;4(1):45-55.	Review/Other-Dx	N/A	To review using intravascular US as an imaging modality for endograft deployment and the ways in which this new technology has influenced the clinical application of endovascular prostheses.	No results stated in abstract.	4
48. American College of Radiology. ACR Appropriateness Criteria® Radiation Dose Assessment Introduction. Available at: http://www.acr.org/~/media/ACR/Documents/AppCriteria/RadiationDoseAssessmentIntro.pdf.	Review/Other-Dx	N/A	Guidance document on exposure of patients to ionizing radiation.	N/A	4

Evidence Table Key

Study Quality Category Definitions

- *Category 1* The study is well-designed and accounts for common biases.
- *Category 2* The study is moderately well-designed and accounts for most common biases.
- *Category 3* There are important study design limitations.
- *Category 4* The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:
  a) the study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);
  b) the study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;
  c) the study is an expert opinion or consensus document.
- M = Meta-analysis

Dx = Diagnostic

Tx = Treatment