Transfemoral Transcatheter Aortic Valve Replacement

Adapted from:

Transfemoral transcatheter aortic valve replacement

Mylotte D, Martucci G, Lange R, Piazza N. Endovascular and Hybrid Therapies for Structural Heart and Aortic Disease, First Edition. Edited by Jacques Kpodonu and Raoul Bonan. 2013 John Wiley & Sons, Ltd.

INTRODUCTION

Somewhat surprisingly, transcatheter treatment of valvular heart disease was first conceived as far back as 1965. Davies devised a catheter-mounted cone-shaped valve as a potential therapy for aortic insufficiency [1], and paved the way for the development of a variety of transcatheter devices for the treatment of aortic insufficiency over the next 25–30 years [2–4]. Real progress in the field was not realized until 1986, when Professor Alain Cribier performed the first balloon aortic valvuloplasty (BAV) for the treatment of severe aortic stenosis [5]. Unfortunately, the impressive acute hemodynamic outcomes were diminished by valve restenosis, and symptoms typically recurred within 6–8 months of therapy [6–12]. Nevertheless, BAV demonstrated, for the first time, that transcatheter treatment of aortic stenosis was feasible, and with refinement could be an effective treatment for the 30–60% of patients who are refused surgery [13–16].

In 2002, some 15 years after performing the first BAV, Cribier implanted the first in-human balloon-expandable transcatheter heart valve. A first generation 23 mm bovine pericardial stent valve developed by Percutaneous Valve Technologies (Fort Lee, NJ), was implanted using a 24 Fr catheter delivery system [17]. The recipient was a 57-year-old man with refractory cardiogenic shock secondary to severe aortic stenosis, who was denied traditional aortic valve surgery (Fig. 14.1). Significant peripheral arterial disease necessitated antegrade implantation using a transvenous approach and transeptal puncture. After valve implantation, the transvalvular aortic gradient was <10 mmHg and the aortic valve area increased to 1.7 cm^2. Based on this initial success, the first series of 40 patients underwent implantation of a modified heart valve, the Cribier–Edwards valve, using an antegrade transeptal approach [18].

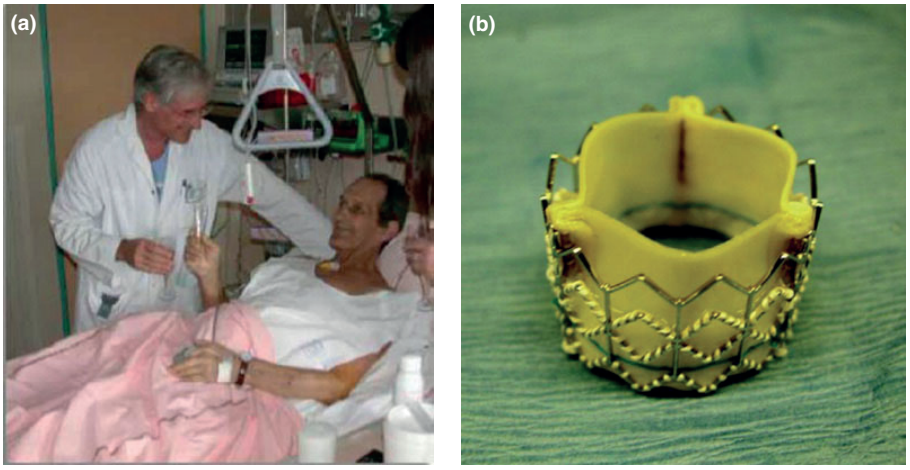


Fig. 14.1 (a) The first patient to undergo transcatheter aortic valve implantation (April 16, 2002) using the first generation balloon expandable valve (b) that housed trileaflet bovine pericardial leaflets. Image courtesy of the PCR-EAPCI Percutaneous Interventional Cardiovascular Medicine Textbook, 2012, Europa Publishing.

The challenging nature of antegrade transvenous transcatheter aortic valve implantation, and not infrequent hemodynamic instability encountered due to mitral valve tethering and injury, motivated the development of alternative implantation strategies. The retrograde approach via the femoral artery (transfemoral) and the antegrade approach via the apex of the left ventricle (transapical) were developed using the Edwards LifeSciences system (Irvine, CA) [19].

In July 2004, the CoreValve ReValving system (Paris, France) was first implanted (Fig. 14.2) [20]. Initially, these procedures were complex and time consuming, requiring general anesthesia, cardiopulmonary bypass, and surgical cutdown of the femoral artery. However, downsizing of the delivery catheter and increasing operator experience soon saw the majority of procedures being performed percutaneously, under conscious sedation and local anesthesia, without cardiopulmonary support [21].

Fig. 14.2 The first generation CoreValve ReValving System bioprosthesis housing trileaflet bovine pericardial leaflets. The current third generation Medtronic CoreValve bioprosthesis houses leaflets made of porcine pericardium.

A wealth of knowledge has been acquired with respect to patient selection, procedural techniques, and post-procedure care over the last 10 years. These refinements have improved patient safety and procedural outcomes.

PATIENT SELECTION

Transcatheter aortic valve replacement (TAVR) is currently indicated for high or prohibitive surgical risk patients with symptomatic calcific aortic stenosis (aortic valve area <1.0 cm^2) requiring aortic valve replacement.

Clinical criteria

TAVR was developed to treat the high or prohibitive surgical risk patient. This risk is usually quantified using several cardiac surgical risk algorithms [22–34]. However, these risk models were developed using low to intermediate surgical risk patients and their reliability when applied to high or prohibitive surgical risk patients is unclear [35–38]. To date, the logistic EuroScore and the STS (Society of Thoracic Surgeons) Predicted Risk of Mortality score have directed enrolment of patients into TAVR trials [22,33]. A logistic EuroScore ≥15% or STS score ≥10% define the high surgical risk patient for trial inclusion [39,40]. The logistic EuroScore tends to overestimate the observed mortality risk of high-risk patients by a factor of 2–3 [35,36], and therefore the STS score may be more reliable [58]. Evidently, clinical judgment should always supersede surgical risk algorithms [41].

Anatomical criteria

Pre-procedure screening of the peripheral arterial vasculature and aortic valvular complex (left ventricular outflow tract, aortic annulus, sinus of Valsalva, sinotubular junction, ascending aorta) is required. This is achieved using a combination of transthoracic and transesophageal echocardiography (TTE, TEE), multislice computed tomography (MSCT), and fluoroscopy/angiography [42]. These data determine the most appropriate access route (i.e. transfemoral, subclavian, apical, or direct aortic) and the transcatheter valve size [43].

Assessment of the arterial vasculature

Peripheral contrast angiography is the most practical, readily available, and cost effective modality for assessing the peripheral vasculature. In contrast, MSCT is associated with a higher contrast load, higher radiation exposure, and is more expensive. However, MSCT provides greater appreciation of vessel size, tortuosity, and calcific burden (Fig. 14.3) [44,45]. Using contrast angiography, a SFAR ratio (i.e. outer sheath diameter to femoral artery minimal luminal diameter ratio) of ≥1.05 was identified as a predictor of Valvular Academic Reseach Consortium (VARC) major vascular complications and 30-day mortality [46,47]. This ratio increased to 1.10 in non-calcified vessels and decreased to 1.00 in the presence of calcium. The utility of the SFAR criteria in MSCT is unclear.

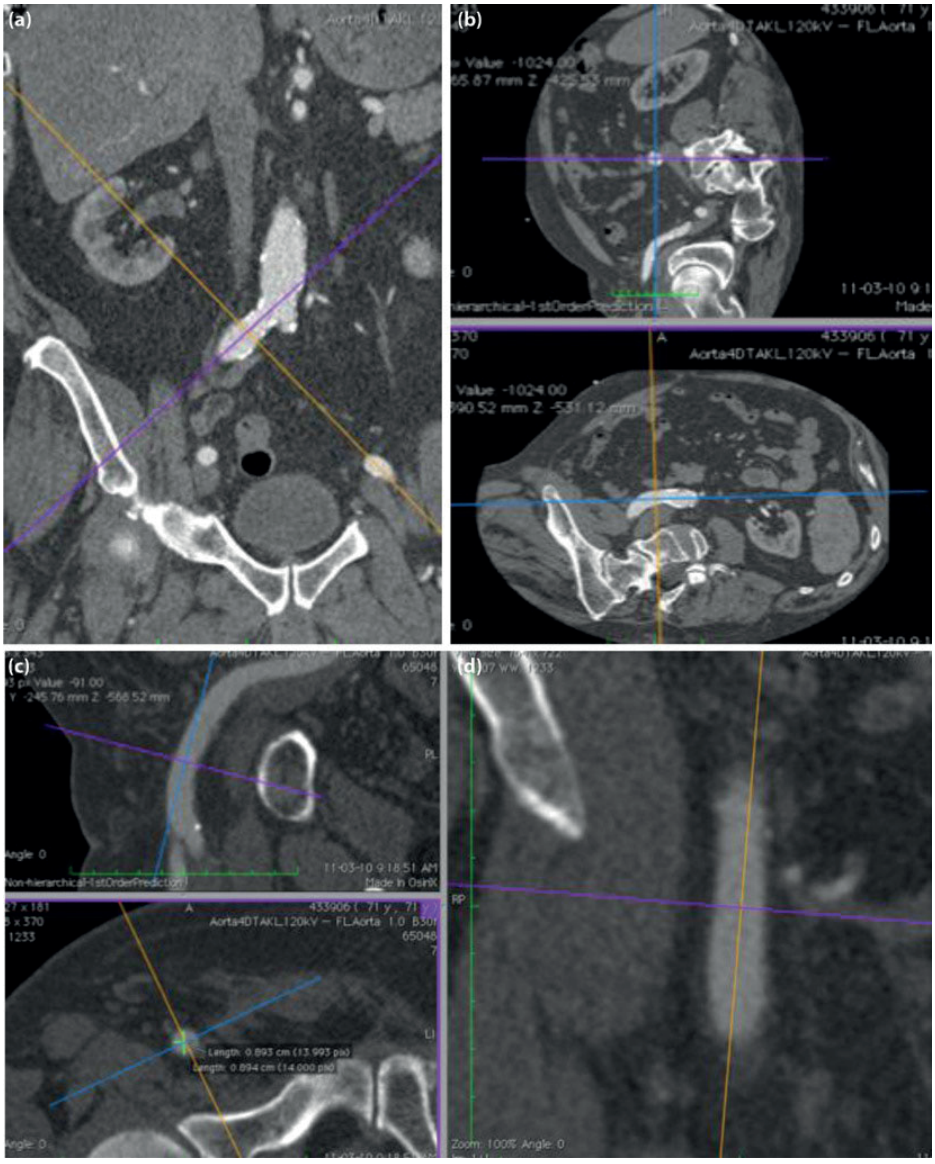


Fig. 14.3 MSCT scans provide the ability for 3D multiplanar reconstructions and therefore can provide superior information about minimum vessel diameter, tortuosity, and degree of calcification than a peripheral angiogram. (a, b) Cross-sectional measurements of the right common iliac artery. (c, d) Cross-sectional measurements of the right common femoral artery at the intended puncture site. Image courtesy of the PCR-EAPCI Percutaneous Interventional Cardiovascular Medicine Textbook, 2012, Europa Publishing.

Assessment of the aortic valve annulus

For the purposes of TAVR, the aortic valve annulus corresponds to a virtual ring formed by junction of the basal attachment points of the leaflets within the left ventricle (Fig. 14.4)

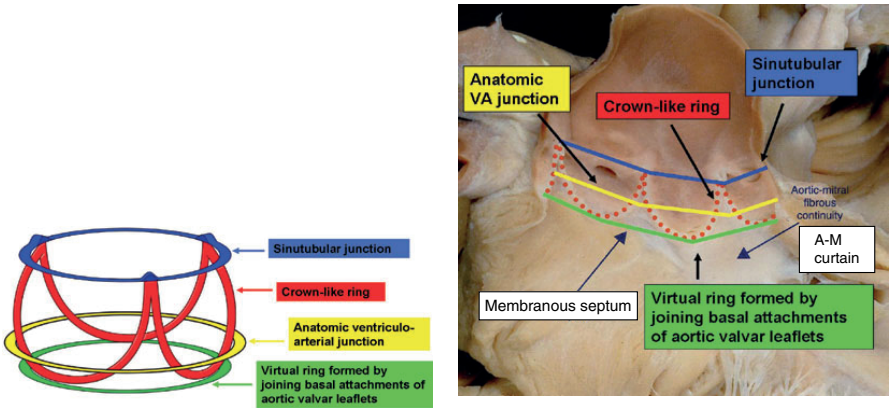


Fig. 14.4 The aortic root extends from the basal attachment points of the aortic valve leaflets (aortic annular plane) to their superior attachment points at the level of the sinutubular junction. There are three circular rings within the aortic root: (i) a virtual ring (i.e. without histologic demarcation) formed by joining the basal attachments of the aortic valvular leaflets; (ii) a ring at the anatomic ventriculo-arterial junction identified histologically as the transformation zone between aortic wall tissue and ventricular myocardium; and (iii) a ring at the sinutubular junction found at the apical attachment points of the aortic valvular leaflets. The "curtain-like" attachment line of the aortic valvular leaflets forms the crown-like ring. For purposes of transcatheter aortic valve sizing, it is the diameter of the virtual basal ring that is taken into consideration. Image courtesy of the PCR-EAPCI Percutaneous Interventional Cardiovascular Medicine Textbook, 2012, Europa Publishing.

[48]. This plane represents the transition from the left ventricular outflow tract into the aortic root. The non-circular shape of the aortic valve annulus has generated much debate about how best to measure its diameter for the purposes of transcatheter aortic valve size selection (Fig. 14.5) [49–51]. Currently, MSCT appears to be the most suitable method for assessment of aortic annulus dimensions. MSCT multiplanar reconstructions provide coronal, sagittal, and axial images of the aortic root [52,53]. On the axial view, the maximum and minimum diameter, perimeter, and area of the annulus can be measured. According to MSCT data, the mean difference between the maximum and minimum diameter of the non-circular aortic annulus is 6.5 mm (95% confidence interval, 5.7–7.2) [49,50]. Depending on the orientation, two-dimensional echocardiography appreciates only one view of the aortic annulus, and usually underestimates the annulus diameter with respect to MSCT. With this in mind, the use of two-dimensional measurements (TEE, TEE, contrast aortography) for transcatheter valve sizing is potentially problematic. Nevertheless, two-dimensional echocardiography remains the most commonly used method to assess the aortic valve annulus diameter, though a shift towards MSCT is emerging.

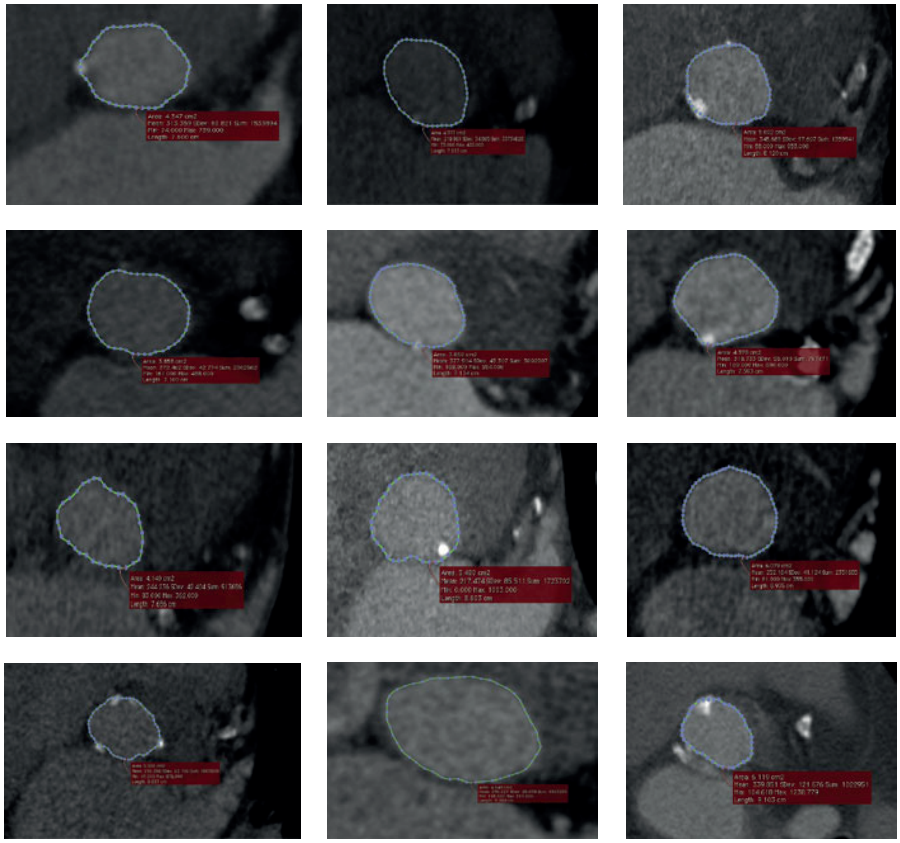


Fig. 14.5 MSCT axial cuts of the aortic annulus from 12 patients demonstrating that the aortic annulus is in fact non-circular. The difference between the maximum and minimum diameter measurements of the aortic annulus is on average 6.5 mm with a standard deviation of approximately 2 mm. The non- circularity of the aortic annulus limits applicability of two-dimensional imaging in estimating the annulus diameter for transcatheter valve sizing. Image courtesy of the PCR-EAPCI Percutaneous Interventional Cardiovascular Medicine Textbook, 2012, Europa Publishing.

APPROVED DEVICE DESCRIPTION

Current TAVR systems consist of three components: (i) the loading system; (ii) the delivery catheter; and (iii) the bioprosthetic aortic valve.

Edwards NovaFlex transfemoral system

The Edwards NovaFlex transfemoral system comprises the Edwards Sapien XT transcatheter heart valve (THV), the NovaFlex delivery system, the Edwards eSheath introducer sheath set, the Retroflex dilator kit, Retroflex balloon catheter, Crimper, and the Atrion inflation device (Fig. 14.6) [54,55].

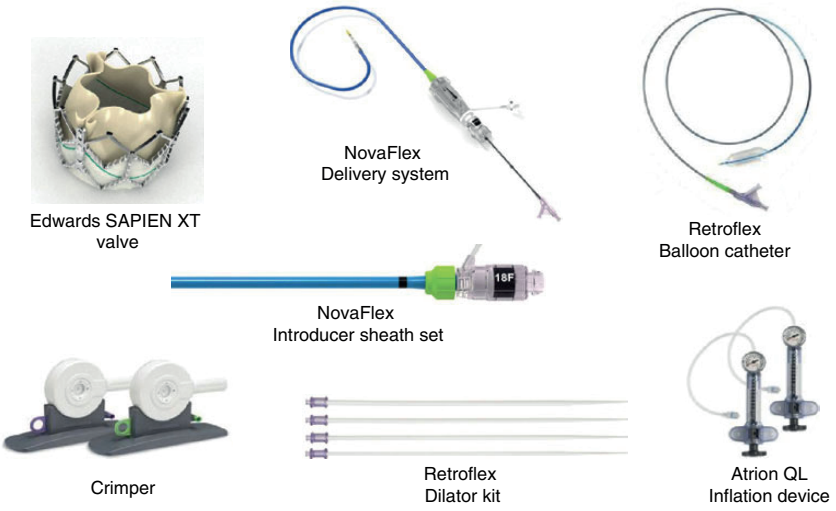


Fig. 14.6 Components of the transfemoral NovaFlex system.

The Edwards Sapien XT THV is a balloon-expandable valve consisting of a radiopaque cobalt-chromium frame, trileaflet bovine pericardial leaflets, and polyethylene terephthalate fabric skirt. The leaflets are manufactured according to *matching technology* and the Edwards Thermafix anticalcification process. The Edwards Sapien XT THV is currently available in four sizes (20, 23, 26, and 29mm) and can be implanted in native annuli with diameters of 16–27 mm (Fig. 14.7). Novel features of the delivery system include: (i) the deflectable NovaFlex delivery catheter, which has a tapered distal tip to facilitate crossing the native aortic valve; and (ii) the Edwards eSheath with dynamic expansion mechanism (DEM) that allows the sheath to transiently expand as the delivery system is advanced. The eSheath has an outer diameter of 6.6 mm (20 Fr) and 7.2 mm (21–22 Fr) for implantation of the 23 and 26 mm THVs, respectively.

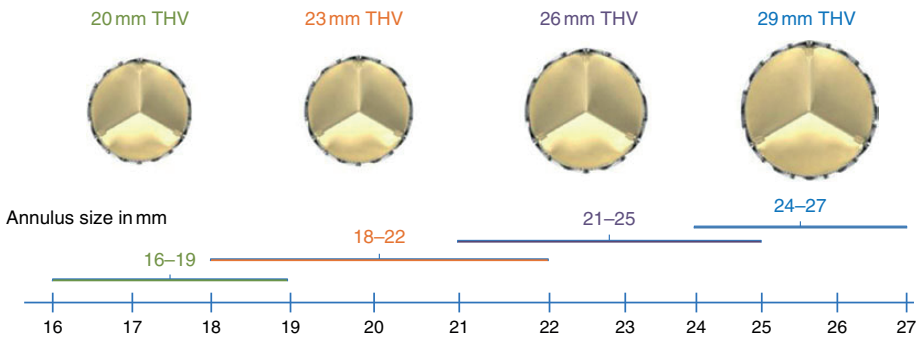


Fig. 14.7 The Edwards Sapien XT showing three of the available sizes.

Medtronic CoreValve system

The Medtronic CoreValve System comprises the CoreValve bioprosthesis, AccuTrak delivery catheter system, and a disposable loading system (Fig. 14.8).

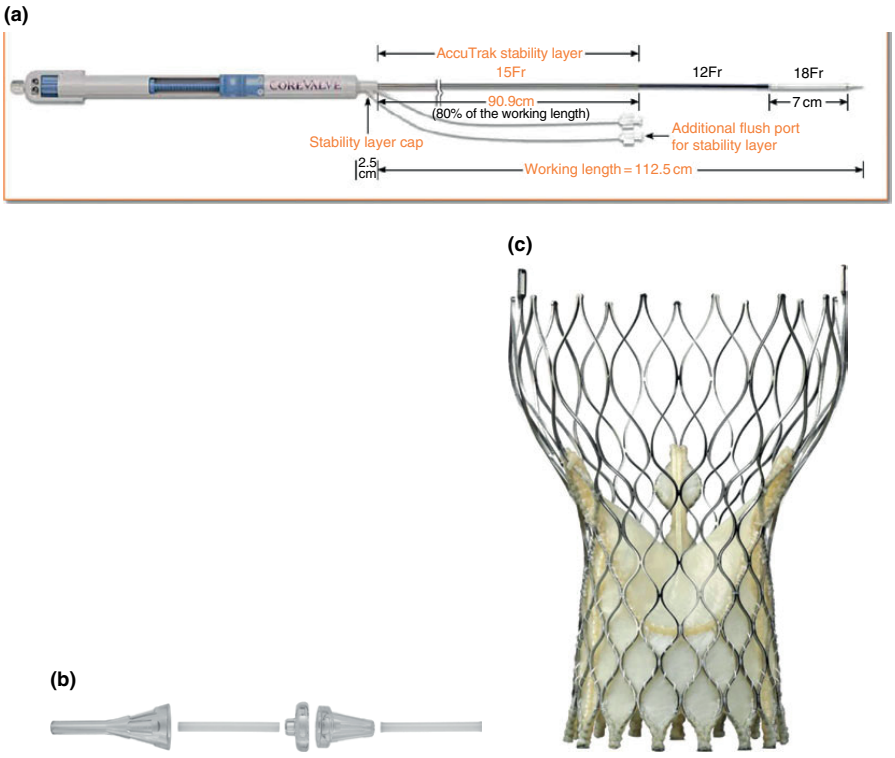


Fig. 14.8 The Medtronic CoreValve system comprises (a) the AccuTrak delivery catheter, (b) the five-piece disposable loading system, and (c) the bioprosthetic valve.

The current (third generation) Medtronic CoreValve bioprosthesis is a self-expandable valve manufactured from a radiopaque nitinol support frame, trileaflet porcine pericardial leaflets, and porcine pericardium fabric skirt. From 2012, the valve leaflets will undergo tissue treatment with alphaamino-oleic acid to reduce calcium deposition [56]. The nitinol support frame is a diamond cell pattern with various strut lengths and widths designed to expand to a non-uniform cylindrical "hour-glass" shape with three distinctive structure–function levels (Fig. 14.9). The inflow section has high radial force to anchor and seal against the native outflow tract and aortic valve to minimize paravalvular aortic regurgitation. The middle section houses the leaflets and has high hoop strength to minimize deformation and ensure optimal leaflet geometry. The outflow section sits in the ascending aorta, has low radial force, and functions to orient the prosthesis in the direction of blood flow.

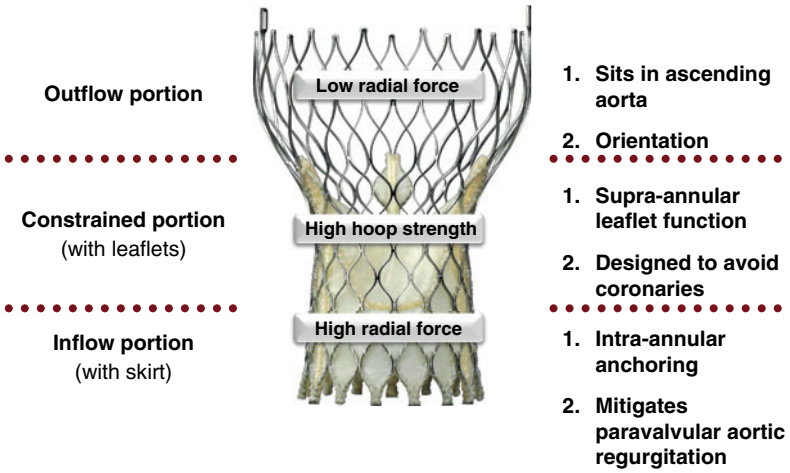


Fig. 14.9 The CoreValve bioprosthesis is characterized as a self-expanding multilevel frame with three distinct areas of form and function: (i) the inflow portion of the frame has high radial force and functions to anchor the prosthesis against the aortic annulus and aortic valve leaflets and together with the skirt creates a seal to mitigate paravalvular aortic regurgitation. (ii) The constrained portion of the frame houses the leaflets and has high hoop strength thereby resisting deformation and maintaining optimal leaflet geometry. Furthermore, this portion is constrained and was designed to avoid the coronary arteries. (iii) The outflow portion of the frame has low radial force and sits in the ascending aorta and was designed to orient the prosthesis in the direction of blood flow.

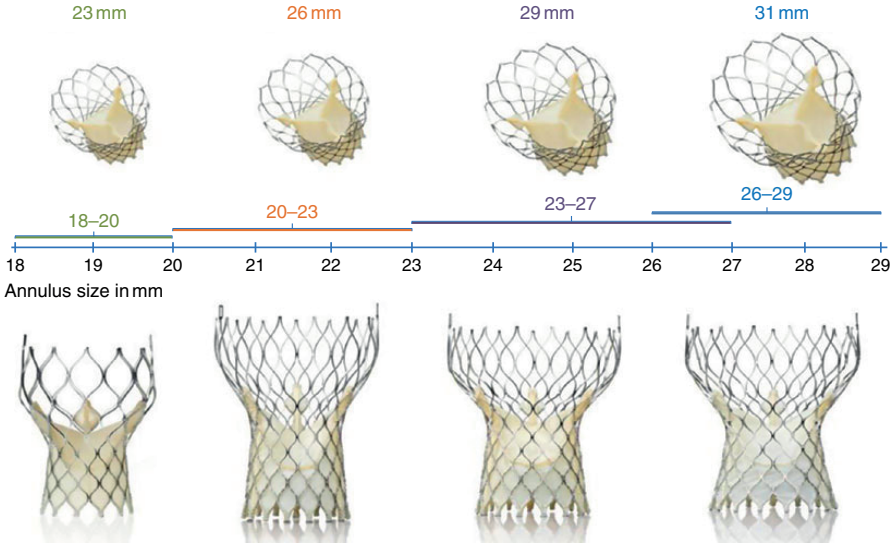


Fig. 14.10 The Medtronic CoreValve showing the four sizes currently available; in 2012.

The CoreValve is available in four sizes (23, 26, 29, and 31 mm) and can be implanted in native annuli with diameters ranging from 20 to 29 mm (Fig. 14.10). It can be implanted via the femoral artery, subclavian artery (57–59), and through a direct aortic access. The Accu-Trak delivery catheter provides greater stability and precision during valve deployment than its predecessor and has an outer diameter of 18 Fr at its distal end (Fig. 14.11) [60].

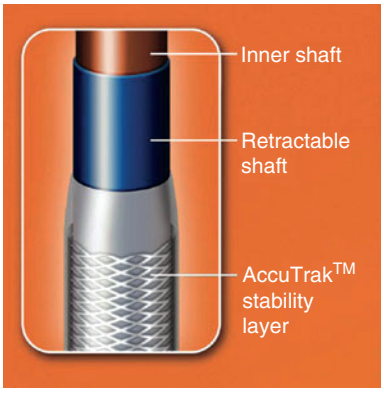


Fig. 14.11 The AccuTrak stability layer is an additional layer that isolates the retractable delivery sheath from the introducer and patient anatomy, thus providing a stable platform for deployment. The aim of the AccuTrak stability layer is to mitigate the forward motion (i.e. towards the ventricle) of the prosthesis during deployment which was characteristic of the predecessor generation of delivery catheter.

TRANSFEMORAL TAVR: PROCEDURAL STEPS

The generic steps involved in performing TAVR are outlined below [61,62].

1 Anesthesia: General or local anesthesia with mild sedation can be successfully used during TAVR [63–73].

2 Anticoagulation: Administer heparin to achieve and maintain an activated clotting time between 250 and 300 seconds. Typically, patients are loaded with 300 mg clopidogrel 24 hours prior to the procedure.

3 Antibiotic prophylaxis: Performed according to hospital protocol.

4 Preparation of the prosthesis: Both bioprostheses are gently agitated in sterile physiologic saline to remove the glutaraldehyde preservative. They are subsequently mounted and/or crimped onto the delivery system.

5 Temporary pacemaker implantation: A temporary pacemaker lead is placed into the right ventricle, and pacemaker function is assessed under rapid pacing, 160–180 beats/minute, such that systemic arterial pressure is reduced below 60 mmHg.

6 Supra-aortic angiogram: A pigtail catheter is placed in the non-coronary sinus to perform a supra-aortic angiogram. The C-arm is angulated to where the nadir of all three leaflets is in one plane, perpendicular to the viewing angle. This is typically located in a left anterior oblique (approximately 10°) with some cranial or caudal (0–15°) angulation. Several ancillary devices can be used to facilitate the optimal viewing angle for implantation [74–77].

7 Vascular access: Vascular access may be performed using a surgical arterial cutdown or percutaneously with aid of pre-closure vascular devices [78]. Vascular pre-closure of the femoral arterial access site can be accomplished with one 10 Fr Prostar XL percutaneous vascular surgical system (Abbott, Park, IL) or two 6 Fr Perclose ProGlide suture-mediated closure system (Abbott, Park, IL). A single puncture of the anterior wall of the common femoral artery is recommended to avoid pre-closure vascular device failure. Contralateral contrast injections and ultrasound-guided puncture can assist vascular puncture.

8 Vascular introducer sheath: Introduction and advancement of the large bore vascular introducer sheath should be performed under fluoroscopic guidance over a stiff guide wire (Amplatz Extra-stiff or Super-stiff). Any resistance encountered while advancing the sheath should be carefully evaluated in order to avoid vascular complications.

9 Crossing the native aortic valve: A variety of catheters can be used to cross the native aortic valve. The Amplatz left 2 is usually selected in patients with an enlarged or a horizontal aortic root whereas the Amplatz left 1 is preferred in those with a small or vertical aortic root. Straight-tipped guide wires should be used to cross the valve. Once crossed, the straight guide wire is exchanged for a pre-shaped long Extra-stiff Amplatz guide wire (Cook Medical, Bloomington, IN; for Edwards Sapien) or Super-stiff Amplatz guide wire (Cook Medical; for Medtronic CoreValve). Pre-shaping of the distal tip is mandatory to reduce the risk of cardiac perforation.

10 Pre-implant balloon aortic valvuloplasty: The Edwards Sapien system is equipped with a custom retroflex 20 or 23 mm × 4 cm balloon dilation kit for the 23 and 26 mm valve sizes, respectively. For the 26 and 29 mm Medtronic CoreValve devices, 22 mm × 4 cm and 25 mm × 4 cm balloons are recommended for pre-implant dilation, respectively.

11 Prosthesis positioning and deployment:

- *Edwards Sapien XT*. The NovaFlex delivery system is advanced through the introducer sheath until the prosthesis exits the sheath. Valve alignment is then performed in the descending aorta and the delivery system is advanced, using the Flex Wheel to trasverse the aortic arch. The native aortic valve is crossed, the Flex Catheter retracted and the prosthesis positioned (50–60% ventricular). Under rapid pacing, to reduce the systolic aortic pressure <50 mmHg, the balloon is inflated, thus deploying the valve. After 4–5 seconds, the balloon is deflated and then the rapid pacing terminated. Finally, the delivery system is de-articulated and retracted across the aortic arch.
- *Medtronic CoreValve*. The CoreValve is advanced across the native aortic valve and is positioned such that its second horizontal radiopaque band lies at the level of the aortic annular plane. In this position, the valve lies approximately 4 mm below the annulus, the target implantation depth (Fig. 14.12). Once a baseline aortogram confirms the position of the prosthesis, the CoreValve is deployed in four steps (Fig. 14.13):
  i. (i)The micro knob is turned clockwise, until the radiopaque ring reaches the second radiopaque band of the prosthesis (Fig. 14.13b). An aortogram is then performed to confirm the prosthesis target depth of 4 mm. At this stage, the prosthesis can be repositioned either more cranial or caudal.
  ii. (ii)The micro knob is turned until the inflow portion of the valve is 40–50% away from contacting the opposite annular surface (Fig. 14.13c). An aortogram is again performed to re-confirm target depth. Again, the prosthesis can be repositioned cranially or caudally.
  iii. (iii)The micro knob is slowly rotated until the inflow portion of the prosthesis comes into contact with the opposite annular surface and an aortogram repeated. Further micro knob rotation is performed until the valve is three-fourths deployed and again an aortogram is performed. At this stage, slight cranial (but *not* caudal) repositioning of the CoreValve can be performed.
  iv. (iv)Further rotation of the micro knob is performed until complete deployment of the CoreValve is achieved.
- The stiff wire is withdrawn towards the tip of the nose cone and the delivery catheter is removed from the left ventricle. The macro knob is then used to recapture the nose cone in the descending aorta.

12 Verify valve position and performance, and rule out potential complications: After valve deployment and removal of the delivery catheters and guide wires, the cardiac rhythm and hemodynamic are carefully assessed. Severe bradycardia or high degrees of atrioventricular block will require immediate temporary pacing. A low aortic diastolic pressure (<35 mmHg), elevated left ventricular end-diastolic pressure, or near equalization of aortic diastolic and left ventricular end-diastolic pressures suggest significant prosthetic valve regurgitation. Valve performance should be assessed using contrast aortography and echocardiography. A supra-

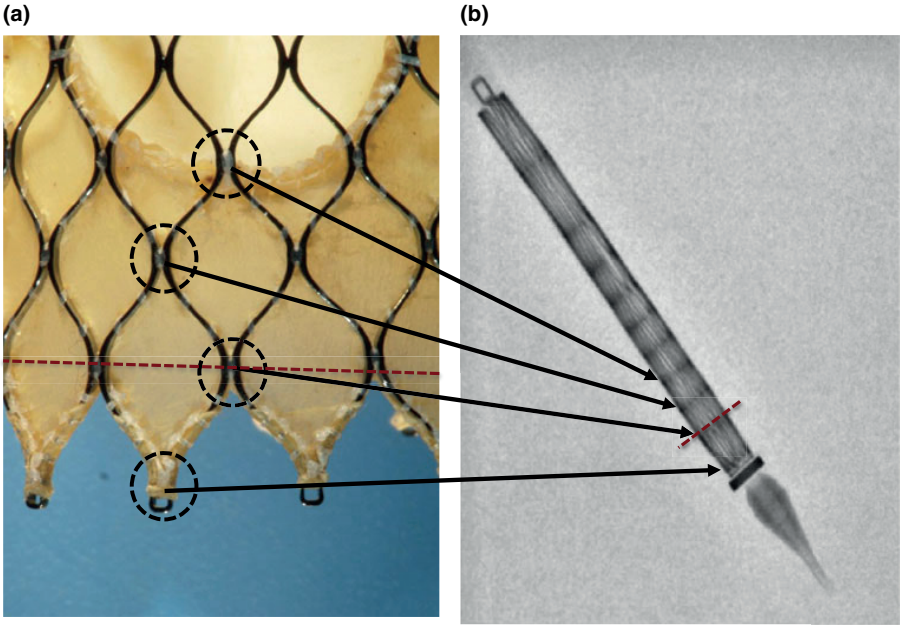


Fig. 14.12 The Medtronic CoreValve frame has a repeating diamond cell configuration. The junction between diamond cells, known as "nodes" (encircled in black in (a)); can be seen as horizontal radiopaque bands on the collapsed frame within the delivery catheter (b). The vertical distance between nodes at the inflow end is approximately 4 mm. The red dotted line represents an implantation depth of 4 mm (i.e. at the second horizontal radiopaque band). These horizontal radiopaque bands are used to guide positioning of the prosthesis during valve deployment.

aortic angiogram in the right anterior oblique (RAO) position is recommended to evaluate valve position, estimate the degree of aortic regurgitation, and confirm patency of the coronary arteries. The severity and origin of aortic regurgitation is optimally assessed with TEE.

13 Vessel closure and hemostasis: Prior to securing the pre-closure sutures, it is strongly recommended that a safety wire be placed from the contralateral femoral artery down the ipsilateral femoral artery beyond the bifurcation [79]. This enables immediate intervention of the ipsilateral femoral artery in case of vascular injury. A final contrast angiography of the peripheral vessels should be performed to confirm hemostasis and rule-out vascular injury.

14 Post-procedural care: All patients should be monitored in an intensive care setting for 24–48 hours after valve implantation. Particular attention should be given to the neurologic status, cardiopulmonary function, renal function, and vascular/ bleeding complications. Continuous telemetry monitoring is recommended for the duration of the hospital stay (4–10 days) [80,81].

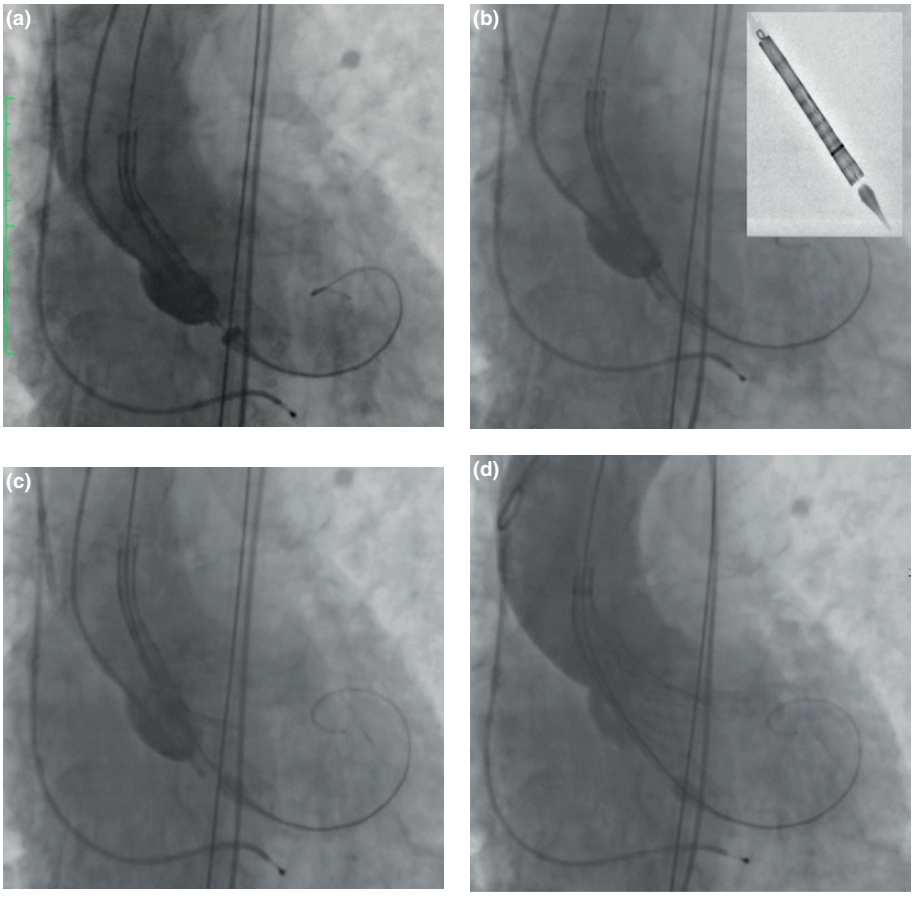


Fig. 14.13 Steps in deployment of the Medtronic CoreValve prosthesis. (a) The unsheathed prosthesis is positioned such that the second horizontal radiopaque band is at the level of the aortic annular plane. (b) Turn the micro knob until the radiopaque ring reaches the second radiopaque band of the prosthesis. (c) Slowly turn the micro knob until the inflow portion of the valve is 40–50% away from contacting the opposite annular surface. (d) Continue to slowly rotate the micro knob until the inflow portion of the prosthesis comes into contact with opposite annular surface. An aortogram may be repeated at this point; otherwise, continue to rotate the micro knob until the prosthesis is three-fourths deployed. Before retracting the delivery catheter verify that the loading hooks of the valve frame are detached from the delivery catheter; this is best appreciated in two orthogonal views. Image courtesy of the PCR-EAPCI Percutaneous Interventional Cardiovascular Medicine Textbook, 2012, Europa Publishing.

TAVR-RELATED COMPLICATIONS

Complications associated with TAVR are classified as cardiac or non-cardiac in origin (Box 14.1).

Box 14.1. Cardiac and non-cardiac complications of transcatheter aortic valve implantation

Cardiac
- Paravalvular aortic regurgitation
- Conduction abnormalities
- Atrial and ventricular arrhythmias
- Coronary obstruction
- Cardiac perforation
- Aortic root rupture
- Prosthetic valve dysfunction
- Embolization
- Transcatheter aortic valve thrombosis
- Transcatheter aortic valve endocarditis
- Mitral regurgitation and mitral valve injury

Non-cardiac
- Stroke
- Vascular injury
- Acute kidney injury

Cardiac complications

Paravalvular aortic regurgitation

A degree of post-implant aortic regurgitation (para-valvular or transvalvular) is observed in 70–90% of TAVR recipients, though less than 5% of cases have moderate to severe aortic regurgitation [82–88]. Mechanisms of aortic regurgitation include: (i) transcatheter valve undersizing [87,89]; (ii) malpositioning [90,91]; (iii) malapposition, under expansion or recoil of the transcatheter valve [92–94]; and (iv) malcoaptation or immobility of the valve leaflets [95–97]. Delayed severe aortic regurgitation has also been reported [98–100]. The mechanism of aortic regurgitation can usually be identified using TEE [85,101,102]. VARC recommends using an integrative echocardiographic approach when quantifying aortic regurgitation [101,102].

Management of significant aortic regurgitation depends on the underlying mechanism, though treatment may include post-implant dilation, implantation of a second valve, or repositioning of the frame using a snare (Fig. 14.14). Conversion to surgical aortic valve replacement is required in less than 1% of cases.

Conduction disturbance

The anatomic proximity of the aortic valvular complex and the conduction system explains the potential for conduction disturbances following TAVR (Fig. 14.15) [48]. Indeed, the average distance between the nadir of the non-coronary aortic valve leaflet and the left bundle branch is only 6.3 ± 2.4 mm (Fig. 14.15) [103]. New-onset left bundle branch block occurs in 30–65% of patients after Medtronic CoreValve implantation and in 7–18% [104–121] after Edwards Sapien implantation [122–124]. The long-term implications of new-onset left bundle branch block after TAVR are unclear however anecdotal evidence suggests that it has a negligible impact on 1-year survival. Approximately 15–47% [104–121] and 4–21% [122–124] of patients require a new permanent pacemaker after CoreValve and Edwards Sapien implantation, respectively.

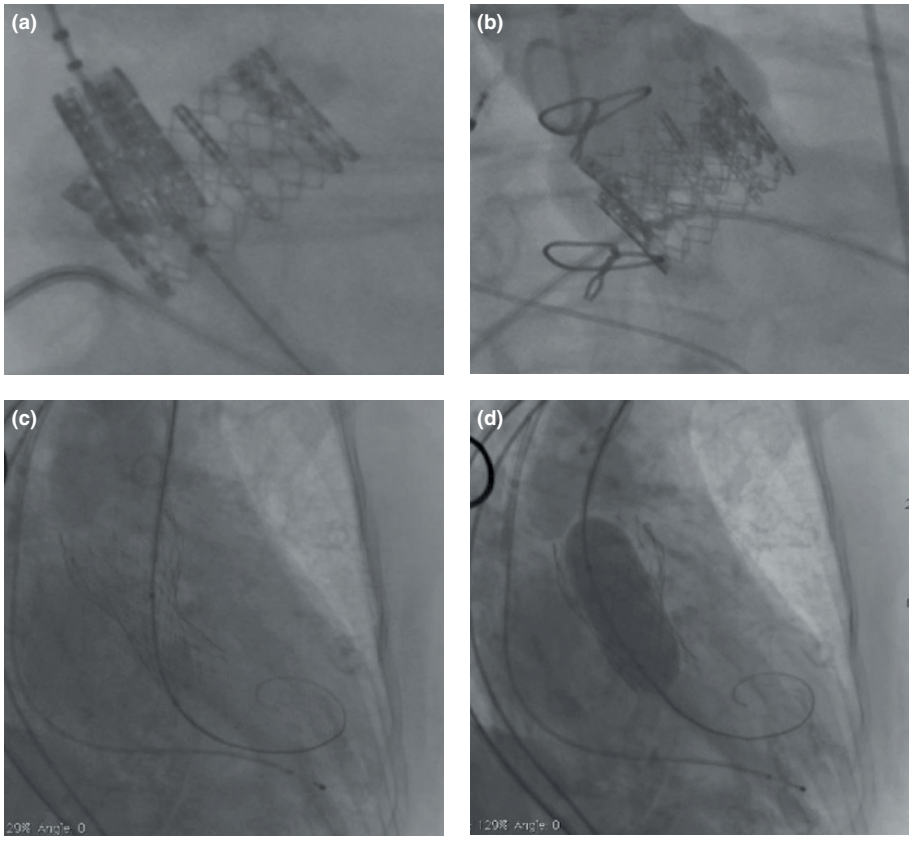


Fig. 14.14 (a) Severe paravalvular aortic regurgitation following low implantation of the Edwards Sapien prosthesis. (b) Transcatheter aortic valve-in-transcatheter aortic valve (TAV-in-TAV) implantation was successful in abolishing paravalvular aortic regurgitation. (c) Despite proper positioning, underexpansion of the CoreValve prosthesis due to severe bulky calcification led to severe paravalvular aortic regurgitation. (d) Post-implant dilation performed during rapid pacing was successful in abolishing the paravalvular aortic regurgitation. Image courtesy of the PCR-EAPCI Percutaneous Interventional Cardiovascular Medicine Textbook, 2012, Europa Publishing.

The most important predictors for new-onset conduction abnormalities after CoreValve implantation include a pre-existing right bundle branch block, baseline QRS duration (ms), and the depth of prosthesis implantation (mm) [104–111,113–115,117–119,121,125,126]. A CoreValve implantation depth of <6 mm has been found to mitigate conduction disturbances [117]. Most patients needing a new permanent pacemaker are identified immediately after valve implantation; however, a small percentage of patients may present with delayed conduction block. Therefore, temporary pacing should be maintained for 48–72 hours, especially after CoreValve implantation. Indications for permanent pacemaker implantation after TAVR are based upon the European Society of Cardiology guidelines [127,128].

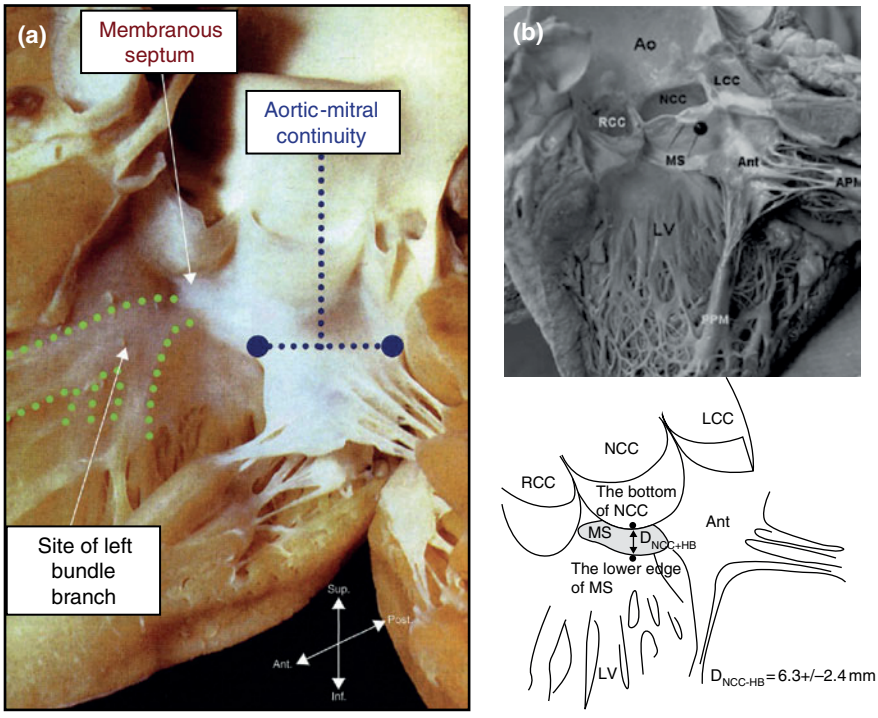


Fig. 14.15 (a) Human heart specimen of the left ventricular cavity, aortic valve, and ascending aorta. Note that the left bundle branch exits at the crest of the ventricular septum just beneath the membranous septum. (b) More specifically, the left bundle branch exits below the membranous septum approximately 6.3 ± 2.4 mm from the bottom of the non-coronary cusp of the aortic valve. Coincidentally, several investigators have noted that conduction abnormalities following CoreValve implantation can be mitigated by implanting the prosthesis ≤6–8 mm from the aortic annular plane. Ant, anterior; Ao, aorta; LCC, left coronary cusp; LV, left ventricle; MS, membranous septum; NCC, non coronary cusp; PPM, posteromedial papillary muscle pacemaker; RCC, right coronary cusp. Green dotted line, site of left bundle branch block; blue dotted line, aortic mitral continuity. Image courtesy of the PCR-EAPCI Percutaneous Interventional Cardiovascular Medicine Textbook, 2012, Europa Publishing.

Cardiac arrhythmias

The reported rates of atrial fibrillation following TAVR vary considerably. A recent observational study found atrial fibrillation in 6% of patients following TAVR, as opposed to 33% in those undergoing surgical aortic valve replacement [129]. In contrast, another study found new-onset atrial fibrillation in 32% of patients undergoing TAVR. Importantly, new-onset atrial fibrillation is associated with higher rates of stroke/system embolism, though not with increased mortality [130].

Life-threatening ventricular arrhythmias (ventricular fibrillation/tachycardia) occur in up to 4% of TAVR patients [19,131]. Multiple ventricular ectopic beats can be induced by the left ventricular guide wire or delivery catheter, and can usually be terminated by repositioning. Defibrillator pads should be placed for the entirety of the procedure and maintained until the patient arrives in the intensive care unit.

Coronary obstruction

Occlusion of the left main coronary following TAVR occurs in less than 1% of cases [132–142]. Unsurprisingly, it frequently induces sudden hemodynamic compromise and death. The diagnosis is usually suspected on the basis of hemodynamics, electrocardiogram (ECG) pattern, and/or contrast aortography. Hemodynamic support and re-establishment of coronary perfusion is critical. The nature and severity of the coronary obstruction and hemodynamic status determines the mode of revascularization (percutaneous or surgical).

Possible mechanisms for coronary obstruction include: (i) impingement of the coronary ostia by the valve support structure; (ii) displacement of the native aortic valve leaflets towards the coronary ostia during valve deployment; and (iii) embolization from calcium, thrombus, air, and/or endocarditis. The width and height of the sinus of Valsalva, the height of the coronary ostia, and the bulkiness of the native leaflets play important roles in the pathogenesis of coronary occlusion following TAVR.

A contrast aortography during balloon aortic valvuloplasty may be performed to evaluate the potential for coronary obstruction. If the aortography suggests an increased risk for coronary obstruction, a safety coronary guide wire can be positioned into the coronary artery with the guiding catheter retracted into the ascending aorta during valve implantation.

Cardiac perforation

Cardiac perforation has been reported in 2–4% of patients undergoing TAVR [131,143,144]. Potential mechanisms include right or left ventricular injury due to the temporary pacemaker lead or stiff guide wire, respectively. Small hypertrophic left ventricular cavities (commonly seen in elderly females), or inadequate pre-shaping or positioning of the left ventricular support wire may increase the risk for this complication. Positioning of the left ventricular stiff guide wire should be performed in the right anterior oblique projection and reassessed throughout the procedure. Cardiac perforation and cardiac tamponade are usually suspected

on the basis of hypotension and/or a new pericardial effusion, and are diagnosed using TTE. Percutaneous pericardiocentesis and reversal of the anticoagulation are recommended.

Aortic annular rupture

Rupture of the annulus or aortic root is rare (<1%). This life-threatening complication is difficult to predict, but typically occurs during balloon inflation (pre-implant balloon aortic valvuloplasty or balloon-expandable valve implantation) (Fig. 14.16). A non-compliant aortic valvular complex, bulky calcification, and aggressive balloon/prosthesis oversizing are possible risk factors. Depending on its location, rupture may result in a ventricular septal defect, left ventricle-to-left atrial or left ventricle-to-right atrial shunt, or communication with the extracardiac space. Contrast aortography usually reveals contrast extravasation confirming the diagnosis. Emergent cardiopulmonary bypass support and surgical exploration is the management of choice.

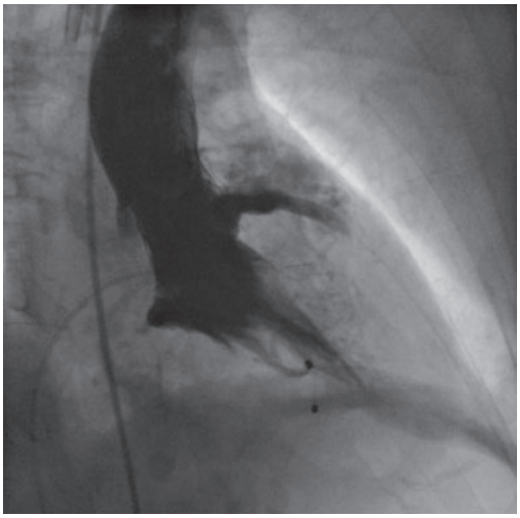


Fig. 14.16 Extravasation of contrast into the pericardial space due to aortic annular rupture. The injury likely occurred immediately after aggressive balloon aortic valvuloplasty. Image courtesy of the PCR-EAPCI Percutaneous Interventional Cardiovascular Medicine Textbook, 2012, Europa Publishing.

Prosthetic valve dysfunction

Prosthetic valve dysfunction may manifest as symptoms and signs of valvular stenosis or regurgitation. Careful clinical history and examination coupled with echocardiography (TTE or TEE) are suggested to evaluate valve dysfunction [101,102]. Prosthetic valve dysfunction is graded as (i) normal, (ii) possible, or (iii) significant according to the VARC criteria [101,102]. To date, there are limited case reports describing degeneration of transcatheter valves [145,146].

Embolization

Transcatheter valve embolization usually occurs during valve implantation and appears to correlate with operator experience. Embolization may be caused by: (i) undersizing the prosthesis; (ii) malplacement of the prosthesis; (iii) improper rapid pacing during valve deployment or post-implant dilation; (iv) entanglement of a guide wire across the struts of the prosthesis during valve re-crossing; (v) entanglement of the nose cone with the inflow portion of the prosthesis upon retrieving the delivery catheter; and (vi) inadequate release of the loading hooks of the frame from the delivery catheter. Delayed embolization, presenting with unexpected hemodynamic compromise and severe aortic regurgitation, has also been described [98,99].

Thrombosis

Valve thrombosis is defined as any thrombus attached to or near an implanted valve that interrupts blood flow, interferes with valve function, or is sufficiently large to warrant treatment. Postmortem studies of patients implanted with the Edwards Sapien and CoreValve prostheses have observed thrombotic material attached to the frame and/or leaflets [147]. To date, transcatheter aortic valve thrombosis has been reported in only three individual case reports [148–150].

Currently, dual antiplatelet therapy (aspirin and clopidogrel) is recommended for 6 months following TAVR, with aspirin continued indefinitely [131,151]. However, a single-center randomized study observed no differences in clinical outcomes between groups who received dual antiplatelet therapy for 3 months versus aspirin alone [152].

Endocarditis

The diagnosis of prosthetic valve endocarditis can be made using the Duke criteria for endocarditis, during reoperation, or on autopsy [101,102]. Several case reports of bacterial or fungal transcatheter aortic valve endocarditis have been reported involving both the Edwards Sapien and Medtronic CoreValve systems [153–159]. These cases underline the importance of adequate dental care prior to TAVR, the importance of pre-procedural antibiotics, and sterile techniques during the procedure.

Mitral valve injury

Mitral valve injury associated with retrograde TAVR is rare. Resistance during the passage of the delivery catheter into the left ventricle or observation of new mitral regurgitation on TEE should raise the suspicion of catheter entanglement within the mitral valve apparatus. Pre-procedural mitral regurgitation can be identified in up 75% of patients [160,161], and improves in approximately one-third of patients, and worsens in one-third following TAVR. Mitral annular calcification and deep implantation of the transcatheter valve into the left ventricular outflow tract have been associated with worsening mitral regurgitation [160–163].

Non-cardiac complications

Stroke

To date, observational series have reported 30-day stroke rates of 0–6% in patients undergoing TAVR [83,131,164–166]. In the randomized PARTNER Cohort A trial, the neurologic event rate (all strokes or transient ischemic attack) was nearly two-fold higher in the TAVR than in the surgical group at 30 days and 1-year follow-up (5.5% versus 2.4% at 30 days, 8.3% versus 4.3% at 1 year) [151]. Similarly, in the randomized PARTNER Cohort B trial, the neurologic event rate was higher in the TAVR than in the medical therapy group at 30 days and 1 year (6.7% versus 1.7% at 30 days, 10.6% versus 4.5% at 1 year). Interestingly, one-third to one-half

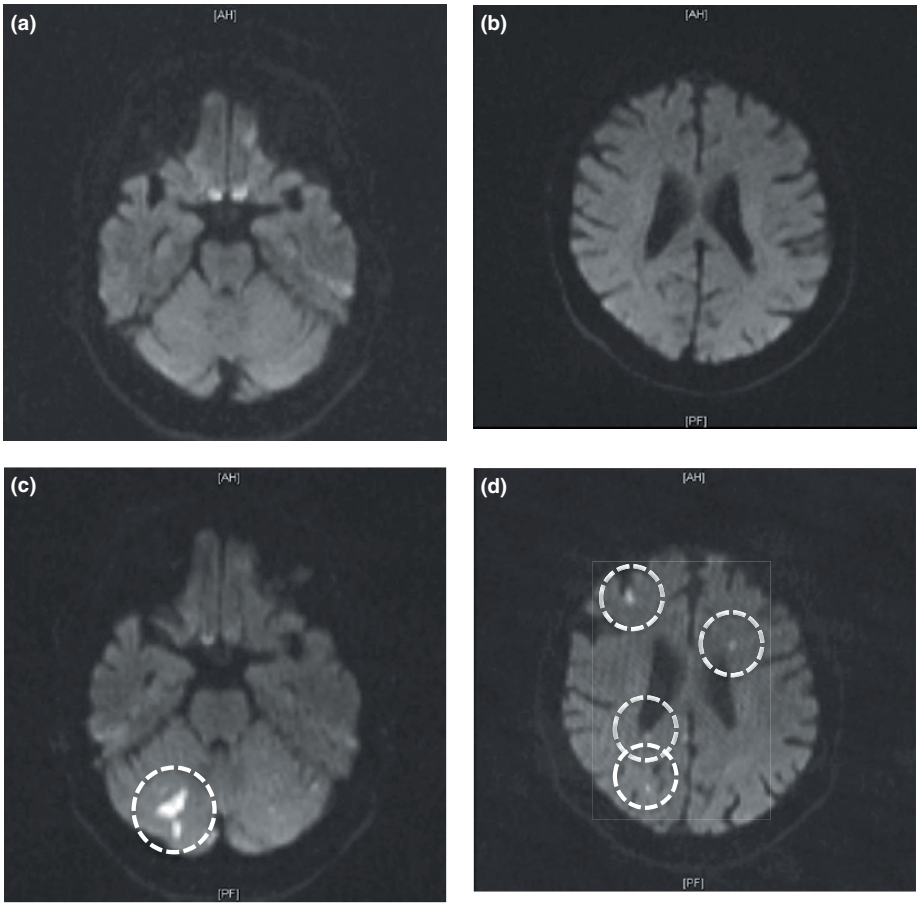


Fig. 14.17 (a, b) Diffusion-weighted MRI of the brain of a 79-year-old patient before undergoing TAVR. (c, d) corresponding diffusion-weighted MRI images of the same patient after a TAVR procedure showing multiple silent cerebral infarcts (encircled in white). Image courtesy of the PCR-EAPCI Percutaneous Interventional Cardiovascular Medicine Textbook, 2012, Europa Publishing.

of strokes occurred between 2 and 30 days after the index procedure [131,151,167]. A history of cerebrovascular disease is an independent predictor of neurologic injury after TAVR [168].

Post-TAVR magnetic resonance imaging (MRI) studies have observed new and multiple silent cerebral infarcts in 68–83% of cases (Fig. 14.17) [169–174]. This suggests that most strokes after TAVR are embolic in nature, a hypothesis corroborated by a recent study using intra-procedural transcranial Doppler which found cerebral microemboli in all patients undergoing transapical TAVR [175]. Cerebral embolic protection devices such as the Embrella (Edwards LifeSciences, Irvine, CA) and Montage System (Claret Medical, Santa Rosa, CA) have been developed to prevent cerebral embolization and have received a European CE mark (Fig. 14.18) [176,177]. These devices have the potential to reduce the incidence of clinical stroke in TAVR recipients [178].

Vascular injury

Vascular complications have been reported in 2–30% of patients undergoing TAVR, and are associated with increased short-term mortality [46,179–182]. Vascular injuries may include dissection, rupture, thrombosis, stenosis, artery avulsion during sheath retraction, failure of vascular pre-closure, arterial-venous fistula, and/or pseudoaneurysms. Femoral and iliac artery complications occur with near equal frequency, though dissections occur more frequently in the femoral artery, and ruptures more common in the iliac artery [46]. Failure of vascular closure devices is an important source of minor vascular complications [180]. Treatment is again cause specific, and includes external femoral artery compression, prolonged balloon inflation, implantation of bare/ covered stents, percutaneous endografts, or surgical repair. Guide wires are easily advanced from the contralateral femoral artery to delivery hemostatic occlusion balloons or stents when needed.

Serious vascular injuries can usually be avoided by: (i) careful vascular screening; (ii) low threshold for using non-femoral access; (iii) consideration for surgical cutdown; (iv) fluoroscopic guidance for advancing devices; and (v) never forcibly advancing materials. Ultrasound-guided femoral artery puncture may also reduce vascular injury [21].

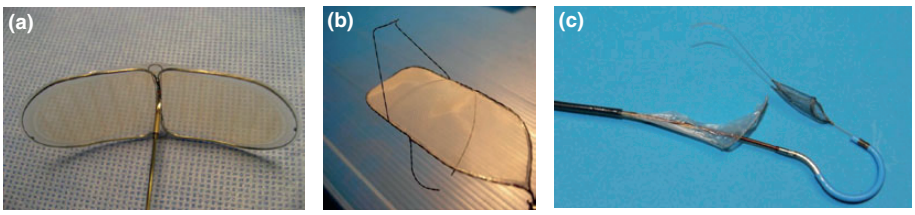


Fig. 14.18 (a) The Embrella device is implanted via a radial artery approach and sits across the aortic arch. (b) SMT embolic deflection device (SMT Research and Development, Herzliya Pituach, Israel) is implanted via a femoral arterial approach and sits across the aortic arch. (c) Montage System (Claret Medical, Santa Rosa, CA) is implanted via a radial approach and each basket sits within a carotid artery.

Acute kidney injury

Chronic kidney failure is present in 10–25% of patients undergoing TAVR. Acute kidney injury (AKI) has been documented in 7–28% of patients following TAVR [80,183–187], and both baseline renal dysfunction and AKI have been associated with increased 30-day and 1-year mortality [183,185,186,188]. A variety of factors are predictive of AKI: history of hypertension, peripheral arterial disease, logistic EuroScore, pre-procedural creatinine level, and post-procedural aortic regurgitation >2+ [80,183–187]. Approximately 100– 120 ml of contrast is used during a TAVR procedure, though the volume of contrast has not been linked to the development of AKI. The need for in-hospital renal replacement therapy has been reported in 1–10% of patients [183–187].

CLINICAL TRIAL OUTCOMES

Uniform definitions for clinical endpoints are of considerable importance when evaluating and summarizing current TAVR data.

Valvular Academic Research Consortium

The VARC was established to arrive at a consensus (i) on the most appropriate clinical endpoints reflecting device and patient effectiveness and safety, and (ii) to standardize the definition of endpoints for valve-related clinical trials [101,102,189].

Summary of TAVR clinical studies

Table 14.1 summarizes the clinical outcomes of selected TAVR studies [39,80,131,151,166, 167,188,190–200].

PARTNER US Trial

The Placement of Aortic TraNscathetER Valve (PARTNER) US Trial was the first prospective, randomized-controlled trial for transcatheter heart valves. This trial consisted of two individually powered patient cohorts (Cohort A and B). In Cohort A, the Edwards Sapien prosthesis was compared with surgical aortic valve replacement in high-risk surgical patients with severe aortic stenosis [151]. In Cohort B, the Edwards Sapien THV was compared to best medical management in inoperable patients with severe aortic stenosis [167].

Cohort B results

In Cohort B, TAVR was superior to medical therapy and/or balloon aortic valvuloplasty for all-cause mortality at 1 year (31% versus 51%, P <0.001, number needed to treat (NNT) = 5) and at 2 years (43% versus 68%, P <0.001, NNT = 4) [167,201]. The observed rate of neurologic events (stroke and transient ischemic attack), were higher in the transcatheter group

Table 14.1 Summary of clinical outcomes with transcatheter aortic valve implantation.

Reference	*Study sample size*	*Prosthesis type*	*Age (years)*	*Logistic EuroScore (%)*	*STS (%)*	*30-day mortality (%)*	*1-year mortality (%)*	*>1 year mortality (%) (as indicated)*	*Stroke (%)*	*MI and/or CO (%)*	*Vascular injury (%)*	*Bleeding (%)*	*Pacemaker implantation (%)*	*Acute renal injury/dialysis* (%)*	*Tamponade (%)*	*New-onset atrial fibrilltion (%)*	*Conversion to surgery (%)*
[193]	244	ES and MC	82.3 ± 7.3	25.6 ± 11.4	18.9 ± 12.8	12.7	–	–	3.6	1.2	7.3	–	11.8	–/1.6*	2.1	–	–
[200]	697	ES and MC	81.4 ± 6.3	20.5 ± 13.2	–	12.4	–	–	2.8	0.4	19.5	–	39.3	–	1.8	–	–
[60]	646	MDT CV	81.0 ± 6.6	23.1 ± 13.8	9.6 ± 3.5	8	–	–	1.9	0.6	1.9	–	9.3	–	1.4	–	0.5
[199]	200	ES and MC	82.0 ± 6.5	24.6 ± 15.3	6.4 ± 4.9	7.5	–	–	4.5	0.5	13.5	35.5	22.5	19/–	1.1	–	–
[196]	70	ES	84.7 ± 7.6	31.7 ± 16.0	9.6 ± 3.5	–	–	38.6 (3-year)	8.6 (3-year)	8.6 (3-year)	–	7.1 (3-year)	7.1 (3-year)	–	–	–	1.4 (3-year)
[80]	150	MC	81 ± 7	12.3 (9.1–18.4)	6.1 (3.7–12.5)	11	–	–	8	1.1	16	26	19	18.0/–	–	–	0
[188]	663	MC	81.0 ± 7.3	23.0 ± 13.7	–	5.9	15	–	1.2	0	2	–	17.4	–	1.2	–	0.8
[151]	348	ES	83.6 ± 6.8	29.3 ± 16.5	11.8 ± 3.3	3.4	24.2	–	4.7	0	17	9.3	3.8	1.2/2.9*	–	8.6	2.5
[81,197]	1038	ES	81.2 ± 6.8	27.4 ± 15.1	–	8.5	23.9	–	2.5	0.6	12.8	–	7.1	–/4.3*	–	–	–
[192]	328	ES and MC	83.1 ± 6.1	28.0 ± 16.0	–	11	–	–	5	–	–	–	13	–/6*	–	–	–
[194]	136	MC	80.9	21.3	9.7	12.5	18.4	–	3.7	2.2	–	–	25	–	1.5	–	–
[190]	504	ES	81.2 ± 6.5	24 ± 16	11 ± 4	8.3	–	29 (2-year)	3.1	1.6	–	–	5.3	–	–	–	1.9
[195]	270	ES	83.3 ± 8.0	–	9.5	9.6	–	–	3.3	–	6.7	–	5.9	6.7/–	2.2	4.4	–
[167]	179	ES	83.1 ± 8.6	26.4 ± 17.2	11.2 ± 5.8	5	30.7	–	2.3	0	30.7	16.8	3.4	–/1.1*	–	0.6	0

CO, coronary occlusion; ES, Edwards Sapien system; MC, Medtronic CoreValue system; MI, myocardial infarction; STS, Society of Thoracic Surgeons.

than in the medical group at 2-year follow-up (16% versus 6%, $P = 0.003$), though the need for hospitalization was 38% lower in the TAVR group compared with the medical group (35% versus 73%, $P < 0.001$). Quality of life, based on the Kansas City Cardiomyopathy Questionnaire (KCCQ) and SF-12 Health Survey, improved more in the transcatheter than standard therapy group at 30-days and 1-year follow-up [202]. At 12-month follow-up, total costs were significantly lower with TAVR compared with medical therapy: $29,352 versus $52,724 ($P < 0.001$) [203]. Incremental life expectancy of 1.9 years was noted with TAVR.

Cohort A results

In Cohort A, TAVR was non-inferior to surgical aortic valve replacement for all-cause mortality at 1 year (24% versus 27%, $P = 0.001$ for non-inferiority) [151]. The rate of neurologic events was higher in the transcatheter group than in the surgical group at 30 days (5.5% versus 2.4%, $P = 0.04$) and at 1 year (8.3% versus 4.3%, $P = 0.04$). The rates of a composite of death from any cause or major stroke were comparable between the transcatheter group and surgical group at 30 days (6.9 versus 8.2%, $P = 0.52$) and at 1 year (26.5 versus 28.0%, $P = 0.68$). Both surgical aortic valve replacement and TAVR improved disease-specific and generic health-related quality of life over 1-year follow-up [204]. For patients eligible for the transfemoral approach, TAVR resulted in substantial quality of life benefit over surgery at 1 month with similar benefits at 6-month and 1-year follow-up.

SPECIFIC PATIENT SUBGROUPS

Failing surgical bioprosthetic valves

Elective redo aortic valve surgery is associated with an operative mortality rate between 2% and 7%, though this increases to more than 30% in high-risk and non-elective patients [205–207]. In excess of 100 successful transcatheter aortic valve-in-surgical aortic valve (TAV-in-SAV) implantations have been reported with the Medtronic CoreValve and Edwards Sapien transcatheter heart valve for failing stented and stentless surgical bioprostheses [208].

Bicuspid valves

Congenital or acquired bicuspid aortic valve stenosis has been considered a contraindication to TAVR. However, several successful case reports have been documented [209–216]. Anecdotally, stenotic bicuspid aortic annuli are larger and more eccentric than stenotic tricuspid aortic valves, and thus MSCT is strongly recommended for transcatheter aortic valve sizing.

Lower surgical risk patients

Although TAVR was initially conceived for the treatment of high surgical risk or inoperable patients, a recent observational report observed a shift toward the selection of lower surgical

risk patients for TAVR [217]. This paradigm shift was associated with significantly better clinical outcomes in the lower (mean STS score 4%) than higher (mean STS score 7%) surgical risk patients undergoing TAVR at 30-day and 6-month follow-up [218]. As further evidence of this move towards lower surgical risk patients, the SURTAVI (SURgical aortic valve replacement versus Transcatheter Aortic Valve Implantation) and PARTNER II trials are expected to randomize intermediate surgical risk patients with an STS score of 4–8% to TAVR or surgical aortic valve replacement.

FUTURE TRANSCATHETER AORTIC VALVE PLATFORMS

Several novel transcatheter aortic valve designs are undergoing human trials. Table 14.2 summarizes these devices.

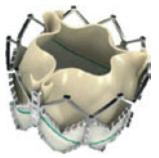
CONCLUSIONS

Transcatheter aortic valve implantation has developed into a relatively mature, safe, and effective therapy for high or prohibitive surgical risk patients with severe aortic stenosis. Device evolution and increasing operator experience have led to improved clinical outcomes. An ever-growing array of clinical studies has improved our understanding of the etiology of cardiac and non-cardiac complications. Meticulous patient selection, procedural techniques, and post-procedure care will further reduce these serious events. Compared with surgical aortic valve replacement, paravalvular aortic regurgitation, stroke, and conduction abnormalities are more common. A variety of novel transcatheter aortic valves are in development.

CONFLICT OF INTEREST STATEMENT

Nicolo Piazza is a consultant and proctor for Medtronic CoreValve.

Table 14.2 A summary of various transcatheter aortic valves and their characteristics.

					
Manufacturer	Edwards SAPIEN XT	Medtronic CoreValve	Direct Flow Medical	Boston Scientific Sadra Medical	St. Jude Medical Portico
Access	TF, TA, DAo	TF, SC, DAo	TF	TF	TF
Deployment	Balloon-expandable	Self-expandable	Inflatable	Self-expandable	Self-expandable
Support structure	Cobalt chromium	Nitinol	Inflatable	Nitinol	Nitinol
Leaflets	Bovine pericardium	Porcine pericardium	Bovine pericardium	Bovine pericardium	Bovine pericardium
Skirt	Polyethylene terephalate	Porcine pericardium	Polyester	Polyurethane	Porcine pericardium
Delivery catheter	18F/19F	18F	18F	18F/20F	18F
R^3	No	Partially	Yes	Yes	Yes
					
Manufacturer	Heart Leaflet Technology	Colibri Heart Valve	Medtronic Engager	Jena Valve Technology	Symetis Acurate System
Access	TF	TF	TA	TA	TA
Deployment	Self-expandable	Balloon-expandable	Self-expandable	Self-expandable	Self-expandable
Support structure	Nitinol	Stainless steel	Nitinol	Nitinol	Nitinol
Leaflets	Porcine pericardium	Porcine pericardium	Bovine pericardium	Porcine aortic root	?
Skirt	Braided polyester	Porcine pericardium	Polyester	Polyurethane	?
Delivery catheter	17F	14F/16F	26F	27F	?
R^3	Yes	No	No	Partially	Yes

REFERENCES

1. Davies H. Catheter mounted valve for temporary relief of aortic insufficiency. Lancet 1965;1:250.
2. Moulopoulos SD, Anthopoulos L, Stamatelopoulos S, et al. Catheter-mounted aortic valves. Ann Thorac Surg 1971;11:423–30.
3. Phillips SJ, Ciborski M, Freed PS, et al. A temporary catheter-tip aortic valve: hemodynamic effects on experimental acute aortic insufficiency. Ann Thorac Surg 1976;21:134–7.
4. Matsubara T, Yamazoe M, Tamura Y, et al. Balloon catheter with check valves for experimental relief of acute aortic regurgitation. Am Heart J 1992;124:1002–8.
5. Cribier A, Savin T, Saoudi N, et al. Percutaneous transluminal valvuloplasty of acquired aortic stenosis in elderly patients: an alternative to valve replacement? Lancet 1986;1:63–7.
6. Drobinski G, Lechat P, Metzger JP, et al. Results of percutaneous catheter valvuloplasty for calcified aortic stenosis in the elderly. Eur Heart J 1987;8:322–8.
7. Serruys PW, Luijten HE, Beatt KJ, et al. Percutaneous balloon valvuloplasty for calcific aortic stenosis. A treatment 'sine cure'? Eur Heart J 1988;9:782–94.
8. Safian RD, Berman AD, Diver DJ, et al. Balloon aortic valvuloplasty in 170 consecutive patients. N Engl J Med 1988;319:125–30.
9. Block PC, Palacios IF. Clinical and hemodynamic follow-up after percutaneous aortic valvuloplasty in the elderly. Am J Cardiol 1988;62:760–3.
10. Berland J, Cribier A, Savin T, et al. Percutaneous balloon valvuloplasty in patients with severe aortic stenosis and low ejection fraction. Immediate results and 1-year follow-up. Circulation 1989;79:1189–96.
11. Letac B, Cribier A, Eltchaninoff H, et al. Evaluation of restenosis after balloon dilatation in adult aortic stenosis by repeat catheterization. Am Heart J 1991;122:55–60.
12. Otto CM, Mickel MC, Kennedy JW, et al. Three-year outcome after balloon aortic valvuloplasty. Insights into prognosis of valvular aortic stenosis. Circulation 1994;89:642–50.
13. Charlson E, Legedza AT, Hamel MB. Decision-making and outcomes in severe symptomatic aortic stenosis. J Heart Valve Dis 2006;15:312–21.
14. Pellikka PA, Sarano ME, Nishimura RA, et al. Outcome of 622 adults with asymptomatic, hemodynamically significant aortic stenosis during prolonged follow-up. Circulation 2005;111:3290–5.
15. Lung B, Cachier A, Baron G, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? Eur Heart J 2005;26:2714–20.
16. Bouma BJ, van Den Brink RB, van Der Meulen JH, et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. Heart 1999;82:143–8.
17. Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation 2002;106:3006–8.
18. Cribier A, Eltchaninoff H, Tron C, et al. Treatment of calcific aortic stenosis with the percutaneous heart valve: mid-term follow-up from the initial feasibility studies: the French experience. J Am Coll Cardiol 2006;47:1214–23.
19. Webb JG, Chandavimol M, Thompson CR, et al. Percutaneous aortic valve implantation retrograde from the femoral artery. Circulation 2006;113:842–50.
20. Hijazi Z, Ruiz C, Bonhoeffer P, et al. Transcatheter Valve Repair, 1st edn. New York: Informa Healthcare, 2006.
21. de Jaegere P, van Dijk L, Laborde JC, et al. True percutaneous implantation of the CoreValve aortic valve prosthesis by the combined use of ultrasound guided vascular access, Prostar XL and the TandemHeart. Eurointervention 2007;2:500–5.

22. O'Brien SM, Shahian DM, Filardo G, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 2 – isolated valve surgery. Ann Thorac Surg 2009;88: S23–42.
23. Kuduvalli M, Grayson AD, Au J, et al. A multi-centre additive and logistic risk model for in-hospital mortality following aortic valve replacement. Eur J Cardiothorac Surg 2007;31:607–13.
24. Hannan EL, Wu C, Bennett EV, et al. Risk index for predicting in-hospital mortality for cardiac valve surgery. Ann Thorac Surg 2007;83:921–9.
25. Rankin JS, Hammill BG, Ferguson TB, Jr, et al. Determinants of operative mortality in valvular heart surgery. J Thorac Cardiovasc Surg 2006;131:547–57.
26. Nilsson J, Algotsson L, Hoglund P, et al. Comparison of 19 pre-operative risk stratification models in open-heart surgery. Eur Heart J 2006;27:867–74.
27. Jin R, Grunkemeier GL, Starr A. Validation and refinement of mortality risk models for heart valve surgery. Ann Thorac Surg 2005;80:471–9.
28. Ambler G, Omar RZ, Royston P, et al. Generic, simple risk stratification model for heart valve surgery. Circulation 2005;112:224–31.
29. Nowicki ER, Birkmeyer NJ, Weintraub RW, et al. Multivariable prediction of in-hospital mortality associated with aortic and mitral valve surgery in northern New England. Ann Thorac Surg 2004;77: 1966–77.
30. Gardner SC, Grunwald GK, Rumsfeld JS, et al. Comparison of short-term mortality risk factors for valve replacement versus coronary artery bypass graft surgery. Ann Thorac Surg 2004;77:549–56.
31. Florath I, Rosendahl UP, Mortasawi A, et al. Current determinants of operative mortality in 1400 patients requiring aortic valve replacement. Ann Thorac Surg 2003;76:75–83.
32. Edwards FH, Peterson ED, Coombs LP, et al. Prediction of operative mortality after valve replacement surgery. J Am Coll Cardiol 2001;37:885–92.
33. Nashef SA, Roques F, Michel P, et al. European system for cardiac operative risk evaluation (EuroSCORE). Eur J Cardiothorac Surg 1999;16:9–13.
34. Parsonnet V, Dean D, Bernstein AD. A method of uniform stratification of risk for evaluating the results of surgery in acquired adult heart disease. Circulation 1989;79:I3–12.
35. Osswald BR, Gegouskov V, Badowski-Zyla D, et al. Overestimation of aortic valve replacement risk by Euro-SCORE: implications for percutaneous valve replacement. Eur Heart J 2009;30:74–80.
36. Leontyev S, Walther T, Borger MA, et al. Aortic valve replacement in octogenarians: utility of risk stratification with EuroSCORE. Ann Thorac Surg 2009;87:1440–5.
37. Dewey TM, Brown D, Ryan WH, et al. Reliability of risk algorithms in predicting early and late operative outcomes in high-risk patients undergoing aortic valve replacement. J Thorac Cardiovasc Surg 2008;135:180–7.
38. Brown ML, Schaff HV, Sarano ME, et al. Is the European System for Cardiac Operative Risk Evaluation model valid for estimating the operative risk of patients considered for percutaneous aortic valve replacement? J Thorac Cardiovasc Surg 2008;136:566–71.
39. Lefevre T, Kappetein AP, Wolner E, et al. One year follow-up of the multi-centre European PARTNER transcatheter heart valve study. Eur Heart J 2011;32:148–57.
40. 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;57:1650–7.
41. Piazza N, Wenaweser P, van Gameren M, et al. Relationship between the logistic EuroSCORE and the Society of Thoracic Surgeons Predicted Risk of Mortality score in patients implanted with the CoreValve ReValving system – a Bern-Rotterdam Study. Am Heart J 2010;159:323–9.
42. Delgado V, Ewe SH, Ng AC, et al. Multimodality imaging in transcatheter aortic valve implantation: key steps to assess procedural feasibility. Eurointervention 2010;6: 643–52.

43. Piazza N, de Jaegere P, Manoharan G, et al. Patient selection for the CoreValve ReValving System. In: Serruys P, Piazza N, Cribier A, Webb J, Laborde JC, de Jaegere P (eds) Transcatheter Aortic Valve Implantation: tips and tricks to avoid failure. New York: Informa Healthcare, 2011, p. 82.
44. Nietlispach F, Leipsic J, Al-Bugami S, et al. CT of the ilio-femoral arteries using direct aortic contrast injection: proof of feasibility in patients screened towards percutaneous aortic valve replacement. Swiss Med Wkly 2009;139:458–62.
45. Eltchaninoff H, Kerkeni M, Zajarias A, et al. Aorto-iliac angiography as a screening tool in selecting patients for transfemoral aortic valve implantation with the Edwards SAPIEN bioprosthesis. Eurointervention 2009;5:438–42.
46. Hayashida K, Lefevre T, Chevalier B, et al. Transfemoral aortic valve implantation new criteria to predict vascular complications. JACC Cardiovasc Interv 2011;4:851–8.
47. Piazza N, Serruys PW, Lange R. Getting safely in and out of a transcatheter aortic valve implantation procedure vascular complications according to the valvular academic research consortium criteria. JACC Cardiovasc Interv 2011;4:859–60.
48. Piazza N, de Jaegere P, Schultz C, et al. Anatomy of the aortic valvar complex and its implications for transcatheter implantation of the aortic valve. Circ Cardiovasc Intervent 2008;1:74–81.
49. Schultz CJ, Moelker A, Piazza N, et al. Three dimensional evaluation of the aortic annulus using multislice computer tomography: are manufacturer's guidelines for sizing for percutaneous aortic valve replacement helpful? Eur Heart J 2010;31:849–56.
50. Tops LF, Wood DA, Delgado V, et al. Noninvasive evaluation of the aortic root with multislice computed tomography implications for transcatheter aortic valve replacement. JACC Cardiovasc Imaging 2008;1: 321–30.
51. Ng AC, Yiu KH, Ewe SH, et al. Influence of left ventricular geometry and function on aortic annular dimensions as assessed with multi-detector row computed tomography: implications for transcatheter aortic valve implantation. Eur Heart J 2011;32:2806–13.
52. Schultz C, Moelker A, Tzikas A, et al. The use of MSCT for the evaluation of the aortic root before transcutaneous aortic valve implantation: the Rotterdam approach. Eurointervention 2010;6:505–11.
53. Schultz CJ, Moelker AD, Tzikas A, et al. Cardiac CT: necessary for precise sizing for transcatheter aortic implantation. Eurointervention 2010;6(Suppl G):G6–13.
54. Nietlispach F, Wijesinghe N, Wood D, et al. Current balloon-expandable transcatheter heart valve and delivery systems. Catheter Cardiovasc Interv 2010;75:295–300.
55. Rodes-Cabau J, Delarochelliere R, Dumont E. First-in-man transcatheter aortic valve implantation of a 20-mm edwards SAPIEN XT valve: one step forward for the treatment of patients with severe aortic stenosis and small aortic annulus. Catheter Cardiovasc Interv 2012;79:789–93.
56. Chen W, Schoen FJ, Levy RJ. Mechanism of efficacy of 2-amino oleic acid for inhibition of calcification of glutaraldehyde-pretreated porcine bioprosthetic heart valves. Circulation 1994;90:323–9.
57. Vavuranakis M, Vrachatis DA, Toutouzas K, et al. Successful percutaneous aortic valve implantation via a stenotic left subclavian artery access. Heart Vessels 2010;25:359–62.
58. Munoz-Garcia AJ, Alonso-Briales JH, Such-Martinez M, et al. Left subclavian artery approach to CoreValve aortic prosthesis implantation. Rev Esp Cardiol 2010;63:121–2.
59. Ruge H, Lange R, Bleiziffer S, et al. First successful aortic valve implantation with the CoreValve Re-Valving System via right subclavian artery access: a case report. Heart Surg Forum 2008;11:E323–4.
60. Sarkar K, Ussia GP, Tamburino C. Transcatheter aortic valve implantation for severe aortic regurgitation in a stentless bioprosthetic valve with the core valve revalving system – technical tips and role of the Accutrak system. Catheter Cardiovasc Interv 2011;78:485–90.

61. de Jaegere P, Piazza N, Tzikas A, et al. Implantation of the CoreValve ReValving System. In: Serruys P, Piazza N, Cribier A, Webb J, Laborde J, de Jaegere P (eds) Transcatheter Aortic Valve : tips and tricks to avoid failure, 1st edn. New York: Informa Healthcare, 2011, pp. 183–97.
62. Nietlispach F, Webb J. Implantation of the Edwards SAPIEN valve. In: Serruys P, Piazza N, Cribier A, Webb J, Laborde J, de Jaegere P (eds) Transcatheter Aortic Valve Implantation, 1st edn. New York: Informa Healthcare, 2011, pp. 198–206.
63. Hutchinson N. Sedation vs general anaesthesia for the 'high-risk' patient – what can TAVI teach us? Anaesthesia 2011;66:965–8.
64. Motloch LJ, Rottlaender D, Reda S, et al. Local versus general anesthesia for transfemoral aortic valve implantation. Clin Res Cardiol 2012;101:45–53.
65. Dehedin B, Guinot PG, Ibrahim H, et al. Anesthesia and perioperative management of patients who undergo transfemoral transcatheter aortic valve implantation: an observational study of general versus local/regional anesthesia in 125 consecutive patients. J Cardiothorac Vasc Anesth 2011;25:1036–43.
66. Covello RD, Landoni G, Zangrillo A. Anesthetic management of transcatheter aortic valve implantation. Curr Opin Anaesthesiol 2011;24:417–25.
67. Guinot PG, Depoix JP, Tini L, et al. [Transcutaneous aortic valve implantation: anesthetic and perioperative management]. Ann Fr Anesth Reanim 2011;30:734–42.
68. Vavuranakis M, Voudris V, Vrachatis DA, et al. Transcatheter aortic valve implantation, patient selection process and procedure: two centres' experience of the intervention without general anaesthesia. Hellenic J Cardiol 2010;51:492–500.
69. Guinot PG, Depoix JP, Etchegoyen L, et al. Anesthesia and perioperative management of patients undergoing transcatheter aortic valve implantation: analysis of 90 consecutive patients with focus on perioperative complications. J Cardiothorac Vasc Anesth 2010;24:752–61.
70. Covello RD, Ruggeri L, Landoni G, et al. Transcatheter implantation of an aortic valve: anesthesiological management. Minerva Anestesiol 2010;76:100–8.
71. Behan M, Haworth P, Hutchinson N, et al. Percutaneous aortic valve implants under sedation: our initial experience. Catheter Cardiovasc Interv 2008;72:1012–15.
72. Bergmann L, Kahlert P, Eggebrecht H, et al. Transfemoral aortic valve implantation under sedation and monitored anaesthetic care – a feasibility study. Anaesthesia 2011;66:977–82.
73. Fassl J, Walther T, Groesdonk HV, et al. Anesthesia management for transapical transcatheter aortic valve implantation: a case series. J Cardiothorac Vasc Anesth 2009;23:286–91.
74. Wood DA, Tops LF, Mayo JR, et al. Role of multislice computed tomography in transcatheter aortic valve replacement. Am J Cardiol 2009;103:1295–301.
75. Tzikas A, Schultz C, Van Mieghem NM, et al. Optimal projection estimation for transcatheter aortic valve implantation based on contrast-aortography: validation of a Prototype Software. Catheter Cardiovasc Interv 2010;76:602–7.
76. Dvir D, Kornowski R. Percutaneous aortic valve implantation using novel imaging guidance. Catheter Cardiovasc Interv 2010;76:450–4.
77. 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;3:105–13.
78. Cockburn J, de Belder A, Brooks M, et al. Large calibre arterial access device closure for percutaneous aortic valve interventions: use of the prostar system in 118 cases. Catheter Cardiovasc Interv 2012;79: 143–9.
79. Sharp AS, Michev I, Maisano F, et al. A new technique for vascular access management in transcatheter aortic valve implantation. Catheter Cardiovasc Interv 2010; 75:784–93.

80. Nuis RJ, Piazza N, Van Mieghem NM, et al. In-hospital complications after transcatheter aortic valve implantation revisited according to the valve academic research consortium definitions. Catheter Cardiovasc Interv 2011;78:457–67.
81. Conradi L, Seiffert M, Treede H, et al. Transcatheter aortic valve implantation versus surgical aortic valve replacement: a propensity score analysis in patients at high surgical risk. J Thorac Cardiovasc Surg 2012;143:64–71.
82. Clavel MA, Webb JG, Pibarot P, et al. Comparison of the hemodynamic performance of percutaneous and surgical bioprostheses for the treatment of severe aortic stenosis. J Am Coll Cardiol 2009;53: 1883–91.
83. Himbert D, Descoutures F, Al-Attar N, et al. Results of transfemoral or transapical aortic valve implantation following a uniform assessment in high-risk patients with aortic stenosis. J Am Coll Cardiol 2009;54:303–11.
84. Jilaihawi H, Chin D, Spyt T, et al. Prosthesis-patient mismatch after transcatheter aortic valve implantation with the Medtronic-Corevalve bioprosthesis. Eur Heart J 2010;31:857–64.
85. Moss RR, Ivens E, Pasupati S, et al. Role of echocardiography in percutaneous aortic valve implantation. JACC Cardiovasc Imaging 2008;1:15–24.
86. Jabbour A, Ismail TF, Moat N, et al. Multimodality imaging in transcatheter aortic valve implantation and post-procedural aortic regurgitation: comparison among cardiovascular magnetic resonance, cardiac computed tomography, and echocardiography. J Am Coll Cardiol 2011;58:2165–73.
87. Detaint D, Lepage L, Himbert D, et al. Determinants of significant paravalvular regurgitation after transcatheter aortic valve: implantation impact of device and annulus discongruence. JACC Cardiovasc Interv 2009;2:821–7.
88. Moat NE, Ludman P, de Belder MA, et al. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with severe aortic stenosis: the U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry. J Am Coll Cardiol 2011;58:2130–8.
89. Schultz C, Rossi A, van Mieghem N, et al. Aortic annulus dimensions and leaflet calcification from contrast MSCT predict the need for balloon post-dilatation after TAVI with the Medtronic CoreValve prosthesis. Eurointervention 2011;7:564–72.
90. Ong SH, Mueller R, Gerckens U. Sequential CoreValve implantation for a mal-positioned prosthesis during transcatheter aortic valve implantation. Catheter Cardiovasc Interv 2011;77:1071–5.
91. Zahn R, Schiele R, Kilkowski C, et al. Correction of aortic regurgitation after transcatheter aortic valve implantation of the Medtronic CoreValveTM prosthesis due to a too-low implantation, using transcatheter repositioning. J Heart Valve Dis 2011;20:64–9.
92. Litzler PY, Cribier A, Zajarias A, et al. Surgical aortic valve replacement after percutaneous aortic valve implantation: what have we learned? J Thorac Cardiovasc Surg 2008;136:697–701.
93. Al-Attar N, Ghodbane W, Himbert D, et al. Unexpected complications of transapical aortic valve implantation. Ann Thorac Surg 2009;88:90–4.
94. Takagi K, Latib A, Al-Lamee R, et al. Predictors of moderate-to-severe paravalvular aortic regurgitation immediately after CoreValve implantation and the impact of postdilatation. Catheter Cardiovasc Interv 2011;78:432–43.
95. Al-Attar N, Himbert D, Vahanian A, et al. Severe intra-prosthetic regurgitation by immobile leaflet after transcatheter aortic valve implantation. Eur J Cardiothorac Surg 2011;39:591–2.
96. Zahn R, Schiele R, Kilkowski C, et al. Severe aortic regurgitation after percutaneous transcatheter aortic valve implantation: on the importance to clarify the underlying pathophysiology. Clin Res Cardiol 2010; 99:193–7.

97. Miranda-Balbuena N, Araji OA, Gutierrez-Martin MA, et al. Management of aortic valve dysfunction after transapical approach using the technique "valve after valve". Ann Thorac Surg 2011;92:1102–4.
98. Clavel MA, Dumont E, Pibarot P, et al. Severe valvular regurgitation and late prosthesis embolization after percutaneous aortic valve implantation. Ann Thorac Surg 2009;87:618–21.
99. Baumbach H, Hill S, Hansen M, et al. Severe aortic insufficiency after transapical aortic valve implantation. Ann Thorac Surg 2011;92:728–9.
100. Pagnotta P, Ferrante G, Presbitero P. Rescue "valve in valve" implantation after late onset corevalve cusp rupture leading to acute massive aortic insufficiency. Catheter Cardiovasc Interv 2014;83:E283-6.
101. Leon MB, Piazza N, Nikolsky E, et al. Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the Valve Academic Research Consortium. Eur Heart J 2011;32:205–17.
102. Leon MB, Piazza N, Nikolsky E, et al. Standardized endpoint definitions for Transcatheter Aortic Valve Implantation clinical trials: a consensus report from the Valve Academic Research Consortium. J Am Coll Cardiol 2011;57:253–69.
103. Igawa O, Adachi M, Yano A, et al. Anatomical information for catheter ablation concerning the relationship between the aortic non-coronary cusp and the His-bundle. Circ J 2009;257:73.
104. Aktug O, Dohmen G, Brehmer K, et al. Incidence and predictors of left bundle branch block after transcatheter aortic valve implantation. Int J Cardiol 2011;160:26–30.
105. Baan J, Jr, Yong ZY, Koch KT, et al. Factors associated with cardiac conduction disorders and permanent pacemaker implantation after percutaneous aortic valve implantation with the CoreValve prosthesis. Am Heart J 2010;159:497–503.
106. Bleiziffer S, Ruge H, Horer J, et al. Predictors for new-onset complete heart block after transcatheter aortic valve implantation. JACC Cardiovasc Interv 2010;3:524–30.
107. Calvi V, Puzzangara E, Pruiti GP, et al. Early conduction disorders following percutaneous aortic valve replacement. Pacing Clin Electrophysiol 2009;32(Suppl 1):S126–30.
108. Erkapic D, Kim WK, Weber M, et al. Electrocardiographic and further predictors for permanent pacemaker requirement after transcatheter aortic valve implantation. Europace 2010;12:1188–90.
109. Ferreira ND, Caeiro D, Adao L, et al. Incidence and predictors of permanent pacemaker requirement after transcatheter aortic valve implantation with a self-expanding bioprosthesis. Pacing Clin Electrophysiol 2010;33:1364–72.
110. Fraccaro C, Buja G, Tarantini G, et al. Incidence, predictors, and outcome of conduction disorders after transcatheter self-expandable aortic valve implantation. Am J Cardiol 2011;107:747–54.
111. Guetta V, Goldenberg G, Segev A, et al. Predictors and course of high-degree atrioventricular block after transcatheter aortic valve implantation using the CoreValve Revalving system. Am J Cardiol 2011; 108:1600–5.
112. Haworth P, Behan M, Khawaja M, et al. Predictors for permanent pacing after transcatheter aortic valve implantation. Catheter Cardiovasc Interv 2010;76:751–6.
113. Khawaja MZ, Rajani R, Cook A, et al. Permanent pacemaker insertion after CoreValve transcatheter aortic valve implantation: incidence and contributing factors (the UK CoreValve Collaborative). Circulation 2011;123:951–60.
114. Koos R, Mahnken AH, Aktug O, et al. Electrocardiographic and imaging predictors for permanent pacemaker requirement after transcatheter aortic valve implantation. J Heart Valve Dis 2011;20:83–90.
115. Latsios G, Gerckens U, Buellesfeld L, et al. "Device landing zone" calcification, assessed by MSCT, as a predictive factor for pacemaker implantation after TAVI. Catheter Cardiovasc Interv 2010;76:431–9.

116. Nuis RJ, Van Mieghem NM, Schultz CJ, et al. Timing and potential mechanisms of new conduction abnormalities during the implantation of the Medtronic CoreValve System in patients with aortic stenosis. Eur Heart J 2011;32:2067–74.
117. Piazza N, Nuis RJ, Tzikas A, et al. Persistent conduction abnormalities and requirements for pacemaking six months after transcatheter aortic valve implantation. Eurointervention 2010;6:475–84.
118. Piazza N, Onuma Y, Jesserun E, et al. Early and persistent intraventricular conduction abnormalities and requirements for pacemaking after after percutaneous replacement of the aortic valve. J Am Coll Cardiol Interv 2008;1:310–16.
119. Roten L, Wenaweser P, Delacretaz E, et al. Incidence and predictors of atrioventricular conduction impairment after transcatheter aortic valve implantation. Am J Cardiol 2010;106:1473–80.
120. Rubin JM, Avanzas P, del Valle R, et al. Atrioventricular conduction disturbance characterization in transcatheter aortic valve implantation with the CoreValve prosthesis. Circ Cardiovasc Interv 2011;4: 280–6.
121. Jilaihawi H, Chin D, Vasa-Nicotera M, et al. Predictors for permanent pacemaker requirement after transcatheter aortic valve implantation with the CoreValve bioprosthesis. Am Heart J 2009;157:860–6.
122. Godin M, Eltchaninoff H, Furuta A, et al. Frequency of conduction disturbances after transcatheter implantation of an Edwards Sapien aortic valve prosthesis. Am J Cardiol 2010;106:707–12.
123. Gutierrez M, Rodes-Cabau J, Bagur R, et al. Electrocardiographic changes and clinical outcomes after transapical aortic valve implantation. Am Heart J 2009;158:302–8.
124. Sinhal A, Altwegg A, Pasupati S, et al. Atrioventricular block after transcatheter balloon expandable aortic valve implantation J Am Coll Cardiol Interv 2008;1: 305–309.
125. Koektuerk B, Schaefer U, Bergmann M, et al. Acquired conduction disturbances after percutaneous aortic valve replacement. Circulation 2009;120:S307.
126. Saia F, Lemos PA, Bordoni B, et al. Transcatheter aortic valve implantation with a self-expanding nitinol bioprosthesis: prediction of the need for permanent pacemaker using simple baseline and procedural characteristics. Catheter Cardiovasc Interv 2011;79:712–19.
127. Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/ AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/ NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices) developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. J Am Coll Cardiol 2008;51:e1–62.
128. Vardas PE, Auricchio A, Blanc JJ, et al. Guidelines for cardiac pacing and cardiac resynchronization therapy. The Task Force for Cardiac Pacing and Cardiac Resynchronization Therapy of the European Society of Cardiology. Developed in collaboration with the European Heart Rhythm Association. Europace 2007;9:959–98.
129. Motloch LJ, Reda S, Rottlaender D, et al. Postprocedural atrial fibrillation after transcatheter aortic valve implantation versus surgical aortic valve replacement. Ann Thorac Surg 2012;93(1):124–31.
130. Amat-Santos IJ, Rodes-Cabau J, Urena M, et al. Incidence, predictive factors, and prognostic value of new-onset atrial fibrillation following transcatheter aortic valve implantation. J Am Coll Cardiol 2012; 59(2):178–88.
131. Piazza N, Grube E, Gerckens U, et al. Procedural and 30-day outcomes following transcatheter aortic valve implantation using the third generation (18 F) CoreValve ReValving System – results from the Multicenter, Expanded Evaluation Registry 1-year following CE mark approval. Eurointervention 2008; 4:242–9.

132. Fiorina C, Curello S, Maffeo D, et al. Management of acute left main obstruction after transcatheter aortic valve replacement: the "tunnel technique." Cardiovasc Revasc Med 2012;13(2):142 e5–9.
133. Gurvitch R, Cheung A, Bedogni F, et al. Coronary obstruction following transcatheter aortic valve-in-valve implantation for failed surgical bioprostheses. Catheter Cardiovasc Interv 2011;77:439–44.
134. Kapadia SR, Svensson L, Tuzcu EM. Successful percutaneous management of left main trunk occlusion during percutaneous aortic valve replacement. Catheter Cardiovasc Interv 2009;73:966–72.
135. Kukucka M, Pasic M, Dreysse S, et al. Delayed subtotal coronary obstruction after transapical aortic valve implantation. Interact Cardiovasc Thorac Surg 2011;12:57–60.
136. Webb JG. Coronary obstruction due to transcatheter valve implantation. Catheter Cardiovasc Interv 2009; 73:973.
137. Gogas BD, Zacharoulis AA, Antoniadis AG. Acute coronary occlusion following TAVI. Catheter Cardiovasc Interv 2011;77:435–8.
138. Saia F, Marrozzini C, Marzocchi A. Displacement of calcium nodules of the native valve as a possible cause of left main occlusion following transcatheter aortic valve implantation. J Invasive Cardiol 2011; 23:E106–9.
139. Gerckens U, Latsios G, Mueller R, et al. Left main PCI after trans-subclavian CoreValve implantation. Successful outcome of a combined procedure for management of a rare complication. Clin Res Cardiol 2009;98:687–90.
140. Bagur R, Dumont E, Doyle D, et al. Coronary ostia stenosis after transcatheter aortic valve implantation. JACC Cardiovasc Interv 2010;3:253–5.
141. Bartorelli AL, Andreini D, Sisillo E, et al. Left main coronary artery occlusion after percutaneous aortic valve implantation. Ann Thorac Surg 2010;89:953–5.
142. Stabile E, Sorropago G, Cioppa A, et al. Acute left main obstructions following TAVI. Eurointervention 2010;6:100–5.
143. Lange R, Bleiziffer S, Piazza N, et al. Incidence and treatment of procedural cardiovascular complications associated with trans-arterial and trans-apical interventional aortic valve implantation in 412 consecutive patients. Eur J Cardiothorac Surg 2011;40:1105–13.
144. Webb JG, Pasupati S, Humphries K, et al. Percutaneous transarterial aortic valve replacement in selected high-risk patients with aortic stenosis. Circulation 2007; 116:755–63.
145. Ong SH, Mueller R, Iversen S. Early calcific degeneration of a CoreValve transcatheter aortic bioprosthesis. Eur Heart J 2012;33(5):586.
146. Hammerstingl C, Nickenig G, Grube E. Treatment of a degenerative stenosed CoreValve(®) aortic bioprosthesis by transcatheter valve-in-valve insertion. Catheter Cardiovasc Interv 2012;79(5):748–55.
147. Virmani R, Bonan R, Nakazawa G, et al. Accumulation of worldwide experience with postmortem studies of transcatheter aortic valve implantation – what should we be avoiding? In: Serruys P, Piazza N, Cribier A, Webb J, Laborde J (eds) Transcatheter Aortic Valve Implantation: tips and tricks to avoid failure. New York: Informa Healthcare, 2011, pp. 18–39.
148. Tay EL, Gurvitch R, Wijeysinghe N, et al. Valve thrombosis after transcatheter heart valve implantation. Eurointervention 2011;7:170–1.
149. Kefer J, Astarci P, Renkin J, et al. Images and case reports in interventional cardiology. Thrombotic aortic restenosis after transapical Sapien valve implantation. Circ Cardiovasc Interv 2010;3:289–92.
150. Trepels T, Martens S, Doss M, et al. Images in cardiovascular medicine. Thrombotic restenosis after minimally invasive implantation of aortic valve stent. Circulation 2009;120:e23–4.
151. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med 2011;364:2187–98.

152. Ussia GP, Scarabelli M, Mule M, et al. Dual antiplatelet therapy versus aspirin alone in patients undergoing transcatheter aortic valve implantation. Am J Cardiol 2011;108:1772–6.
153. Head SJ, Dewey TM, Mack MJ. Fungal endocarditis after transfemoral aortic valve implantation. Catheter Cardiovasc Interv 2011;78:1017–19.
154. Carnero-Alcazar M, Maroto Castellanos LC, Carnicer JC, et al. Transapical aortic valve prosthetic endocarditis. Interact Cardiovasc Thorac Surg 2010;11:252–3.
155. Gotzmann M, Mugge A. Fatal prosthetic valve endocarditis of the CoreValve ReValving System. Clin Res Cardiol 2011;100:715–17.
156. Santos M, Thiene G, Sievers HH, et al. Candida endocarditis complicating transapical aortic valve implantation. Eur Heart J 2011;32:2265.
157. Comoglio C, Boffini M, El Qarra S, et al. Aortic valve replacement and mitral valve repair as treatment of complications after percutaneous core valve implantation. J Thorac Cardiovasc Surg 2009;138: 1025–7.
158. Wong DR, Boone RH, Thompson CR, et al. Mitral valve injury late after transcatheter aortic valve implantation. J Thorac Cardiovasc Surg 2009;137:1547–9.
159. Rafiq I, Parthasarathy H, Tremlett C, et al. Infective endocarditis caused by Moraxella nonliquefaciens in a percutaneous aortic valve replacement. Cardiovasc Revasc Med 2011;12:184–6.
160. Tzikas A, Piazza N, van Dalen BM, et al. Changes in mitral regurgitation after transcatheter aortic valve implantation. Catheter Cardiovasc Interv 2010; 75:43–9.
161. De Chiara B, Moreo A, De Marco F, et al. Influence of CoreValve ReValving System implantation on mitral valve function: an echocardiographic study in selected patients. Catheter Cardiovasc Interv 2011; 78:638–44.
162. Durst R, Avelar E, McCarty D, et al. Outcome and improvement predictors of mitral regurgitation after transcatheter aortic valve implantation. J Heart Valve Dis 2011;20:272–81.
163. Hekimian G, Detaint D, Messika-Zeitoun D, et al. Mitral regurgitation in patients referred for transcatheter aortic valve implantation using the Edwards Sapien prosthesis: mechanisms and early postprocedural changes. J Am Soc Echocardiogr 2012;25(2):160–5.
164. Webb JG, Altwegg L, Boone RH, et al. Transcatheter aortic valve implantation: impact on clinical and valve-related outcomes. Circulation 2009;119:3009–16.
165. Rodes-Cabau J, Webb JG, Cheung A, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience. J Am Coll Cardiol 2010;55:1080–90.
166. 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;124:425–33.
167. 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;363:1597–607.
168. Tay EL, Gurvitch R, Wijesinghe N, et al. A high-risk period for cerebrovascular events exists after transcatheter aortic valve implantation. JACC Cardiovasc Interv 2011;4:1290–7.
169. Astarci P, Glineur D, Kefer J, et al. Magnetic resonance imaging evaluation of cerebral embolization during percutaneous aortic valve implantation: comparison of transfemoral and trans-apical approaches using Edwards Sapiens valve. Eur J Cardiothorac Surg 2011;40:475–9.
170. Kahlert P, Knipp SC, Schlamann M, et al. Silent and apparent cerebral ischemia after percutaneous transfemoral aortic valve implantation: a diffusion-weighted magnetic resonance imaging study. Circulation 2010; 121:870–8.

171. Ghanem A, Muller A, Nahle CP, et al. Risk and fate of cerebral embolism after transfemoral aortic valve implantation: a prospective pilot study with diffusion-weighted magnetic resonance imaging. J Am Coll Cardiol 2010;55:1427–32.
172. Rodes-Cabau J, Dumont E, Boone RH, et al. Cerebral embolism following transcatheter aortic valve implantation: comparison of transfemoral and transapical approaches. J Am Coll Cardiol 2011;57: 18–28.
173. Arnold M, Schulz-Heise S, Achenbach S, et al. Embolic cerebral insults after transapical aortic valve implantation detected by magnetic resonance imaging. JACC Cardiovasc Interv 2010;3:1126–32.
174. Fairbairn TA, Mather AN, Bijsterveld P, et al. Diffusion-weighted MRI determined cerebral embolic infarction following transcatheter aortic valve implantation: assessment of predictive risk factors and the relationship to subsequent health status. Heart 2012; 98(1):18–23.
175. Drews T, Pasic M, Buz S, et al. Transcranial Doppler sound detection of cerebral microembolism during transapical aortic valve implantation. Thorac Cardiovasc Surg 2011;59:237–42.
176. Etienne PY, Papadatos S, Pieters D, et al. Embol-x intraaortic filter and transaortic approach for improved cerebral protection in transcatheter aortic valve implantation. Ann Thorac Surg 2011;92:e95–6.
177. Nietlispach F, Wijesinghe N, Gurvitch R, et al. An embolic deflection device for aortic valve interventions. JACC Cardiovasc Interv 2010;3:1133–8.
178. Macdonald S. New embolic protection devices: a review. J Cardiovasc Surg (Torino) 2011;52:821–7.
179. Tchetche D, Dumonteil N, Sauguet A, et al. Thirty-day outcome and vascular complications after transarterial aortic valve implantation using both Edwards Sapien and Medtronic CoreValve bioprostheses in a mixed population. Eurointervention 2010;5:659–65.
180. Van Mieghem NM, Nuis RJ, Piazza N, et al. Vascular complications with transcatheter aortic valve implantation using the 18 Fr Medtronic CoreValve System: the Rotterdam experience. Eurointervention 2010;5:673–9.
181. Ducrocq G, Francis F, Serfaty JM, et al. Vascular complications of transfemoral aortic valve implantation with the Edwards SAPIEN prosthesis: incidence and impact on outcome. Eurointervention 2010;5: 666–72.
182. Kahlert P, Al-Rashid F, Weber M, et al. Vascular access site complications after percutaneous transfemoral aortic valve implantation. Herz 2009;34:398–408.
183. Elhmidi Y, Bleiziffer S, Piazza N, et al. Incidence and predictors of acute kidney injury in patients undergoing transcatheter aortic valve implantation. Am Heart J 2011;161:735–9.
184. Bagur R, Webb JG, Nietlispach F, et al. Acute kidney injury following transcatheter aortic valve implantation: predictive factors, prognostic value, and comparison with surgical aortic valve replacement. Eur Heart J 2010;31:865–74.
185. Nuis RJ, Van Mieghem NM, Tzikas A, et al. Frequency, determinants, and prognostic effects of acute kidney injury and red blood cell transfusion in patients undergoing transcatheter aortic valve implantation. Catheter Cardiovasc Interv 2011;77:881–9.
186. Sinning JM, Ghanem A, Steinhauser H, et al. Renal function as predictor of mortality in patients after percutaneous transcatheter aortic valve implantation. JACC Cardiovasc Interv 2010;3:1141–9.
187. Aregger F, Wenaweser P, Hellige GJ, et al. Risk of acute kidney injury in patients with severe aortic valve stenosis undergoing transcatheter valve replacement. Nephrol Dial Transplant 2009;24:2175–9.
188. Tamburino C, Capodanno D, Ramondo A, et al. Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis. Circulation 2011;123:299–308.
189. Piazza N, Cutlip DE, Onuma Y, et al. Clinical endpoints in transcatheter aortic valve implantation: a call to ARC for standardised definitions. Eurointervention 2009;5:29–31.

190. Kempfert J, Rastan A, Holzhey D, et al. Transapical aortic valve implantation: analysis of risk factors and learning experience in 299 patients. Circulation 2011; 124:S124–9.
191. D'Onofrio A, Rubino P, Fusari M, et al. Clinical and hemodynamic outcomes of "all-comers" undergoing transapical aortic valve implantation: results from the Italian Registry of Trans-Apical Aortic Valve Implantation (I-TA). J Thorac Cardiovasc Surg 2011;142:768–75.
192. Bosmans JM, Kefer J, De Bruyne B, et al. Procedural, 30-day and one year outcome following CoreValve or Edwards transcatheter aortic valve implantation: results of the Belgian national registry. Interact Cardiovasc Thorac Surg 2011;12:762–7.
193. Eltchaninoff H, Prat A, Gilard M, et al. Transcatheter aortic valve implantation: early results of the FRANCE (FRench Aortic National CoreValve and Edwards) registry. Eur Heart J 2011;32:191–7.
194. Grube E, Buellesfeld L, Mueller R, et al. Progress and current status of percutaneous aortic valve replacement: results of three device generations of the CoreValve Revalving System. Circ Cardiovasc Interv 2008; 1:167–75.
195. Gurvitch R, Tay EL, Wijesinghe N, et al. Transcatheter aortic valve implantation: lessons from the learning curve of the first 270 high-risk patients. Catheter Cardiovasc Interv 2011;78:977–84.
196. Gurvitch R, Wood DA, Tay EL, et al. Transcatheter aortic valve implantation: durability of clinical and hemodynamic outcomes beyond 3 years in a large patient cohort. Circulation 2010;122:1319–27.
197. Thomas M, Schymik G, Walther T, et al. Thirty-day results of the SAPIEN aortic Bioprosthesis European Outcome (SOURCE) Registry: a European registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve. Circulation 2010;122:62–9.
198. Walther T, Kempfert J, Rastan A, et al. Transapical aortic valve implantation at 3 years. J Thorac Cardiovasc Surg 2012;143(2):326–31.
199. Wenaweser P, Pilgrim T, Roth N, et al. Clinical outcome and predictors for adverse events after transcatheter aortic valve implantation with the use of different devices and access routes. Am Heart J 2011; 161:1114–24.
200. Zahn R, Gerckens U, Grube E, et al. Transcatheter aortic valve implantation: first results from a multicentre real-world registry. Eur Heart J 2011;32:198–204.
201. Makkar RR
. Two-Year Outcomes of Transcatheter Aortic Valve Replacement (TAVR) in "Inoperable" Patients With Severe Aortic Stenosis: The PARTNER Trial. San Francisco: Transcatheter Cardiovascular Therapeutics (TCT), 2011.
202. Reynolds MR, Magnuson EA, Lei Y, et al. Health-related quality of life after transcatheter aortic valve replacement in inoperable patients with severe aortic stenosis. Circulation 2011;124:1964–72.
203. Reynolds M.
Lifetime Cost Effectiveness of Implantatiob Compared with Standard Care in Inoperable Patients: Results from the PARTNER Trial (Cohort B). New Orleans: American Heart Association, 2011.
204. Cohen D.
Health-Related Quality of Life After Transcatheter vs. Surgical Aortic Valve Replacement in High-Risk Patients with Severe Aortic Stenosis – Results from the PARTNER Trial (Cohort A). San Francisco: Transcatheter Cardiovascular Therapeutics (TCT), 2011.
205. Jamieson WR, Burr LH, Miyagishima RT, et al. Re-operation for bioprosthetic aortic structural failure – risk assessment. Eur J Cardiothorac Surg 2003;24:873–8.
206. Vogt PR, Brunner-LaRocca H, Sidler P, et al. Reoperative surgery for degenerated aortic bioprostheses: predictors for emergency surgery and reoperative mortality. Eur J Cardiothorac Surg 2000;17:134–9.
207. Christiansen S, Schmid M, Autschbach R. Perioperative risk of redo aortic valve replacement. Ann Thorac Cardiovasc Surg 2009;15:105–10.

208. Piazza N, Bleiziffer S, Brockmann G, et al. Transcatheter aortic valve implantation for failing surgical aortic bioprosthetic valve: from concept to clinical application and evaluation (part 2). JACC Cardiovasc Interv 2011;4:733–42.
209. Kochman J, Huczek Z, Koltowski L, et al. Transcatheter implantation of an aortic valve prosthesis in a female patient with severe bicuspid aortic stenosis. Eur Heart J 2012;33(1):112.
210. Wijesinghe N, Ye J, Rodes-Cabau J, et al. Transcatheter aortic valve implantation in patients with bicuspid aortic valve stenosis. JACC Cardiovasc Interv 2010;3: 1122–5.
211. Ferrari E, Locca D, Sulzer C, et al. Successful transapical aortic valve implantation in a congenital bicuspid aortic valve. Ann Thorac Surg 2010;90:630–2.
212. Chiam PT, Chao VT, Tan SY, et al. Percutaneous transcatheter heart valve implantation in a bicuspid aortic valve. JACC Cardiovasc Interv 2010;3:559–61.
213. Unsworth B, Malik I, Mikhail GW. Recognising bicuspid aortic stenosis in patients referred for transcatheter aortic valve implantation: routine screening with three-dimensional transoesophageal echocardiography. Heart 2010;96:645.
214. Delgado V, Tops LF, Schuijf JD, et al. Successful deployment of a transcatheter aortic valve in bicuspid aortic stenosis: role of imaging with multislice computed tomography. Circ Cardiovasc Imaging 2009;2: e12–3.
215. Jilaihawi H, Asgar A, Bonan R. Good outcome and valve function despite Medtronic-corevalve underexpansion. Catheter Cardiovasc Interv 2010;76:1022–5.
216. Raja Y, Holloway B, Doshi SN. Symmetrical expansion of an Edwards Sapien valve in a congenitally bicuspid aortic valve. Heart 2011;97:1113.
217. Lange R, Bleiziffer S, Mazzitelli D, et al. Improvements in transcatheter aortic valve implantation outcomes in lower surgical risk patients: a glimpse into the future. J Am Coll Cardiol 2012;59:280–7.
218. Lange R, Bleiziffer S, Mazzitelli D, et al. Improvements in transcatheter aortic valve implantation outcomes in lower surgical risk patients a glimpse into the future. J Am Coll Cardiol 2011;157(5):860–6.