

Transapical Aortic Valve Implantation: Step by Step

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Purpose. Transapical aortic valve implantation is a new minimally invasive technique for beating heart, off-pump, aortic valve implantation in high-risk patients.

Description. The procedure involves antegrade aortic valve implantation using an oversizing technique with direct access and accurate positioning of a stent-based transcatheter xenograft. Procedural steps include placement of femoral arterial and venous access wires, anterolateral mini-thoracotomy, epicardial pacing, and apical pursestring suture placement. Valve positioning is performed under fluoroscopic and echocardiographic guidance during rapid ventricular pacing.

Evaluation. Patient screening, especially regarding native aortic annulus diameter and pattern of calcification, is essential for success. Since imaging is crucial, implantations are optimally performed in a hybrid operative theater by an experienced team of cardiac surgeons, cardiologists, and anesthesiologists.

Conclusions. The aim of this article is to outline the technical aspects of the new technique of minimally invasive transapical aortic valve implantation.

(Ann Thorac Surg 2009;87:276–83)

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Technology

Transapical aortic valve implantation (TA-AVI) is a minimally invasive, off-pump technique to treat aortic stenosis. The procedure consists of a left anterolateral mini-thoracotomy for direct antegrade surgical access through the apex of the left ventricle, followed by transcatheter aortic valve implantation. Feasibility of TA-AVI has been proven by recent clinical studies [1–3]. The European conformity CE mark of approval for TA-AVI of the Sapien valve (Edwards Lifesciences Inc, Irvine, CA) was granted in January 2008; therefore, several European centers are gaining a rapidly increasing clinical experience with this procedure.

Elderly patients with high-operative risk have been the principal target, patient population for this technique. The TA-AVI is being performed under fluoroscopic and echocardiographic imaging, ideally in a hybrid operating room. Close collaboration between cardiac surgeons, cardiologists, and anesthesiologists forming a specialized dedicated team is highly recommended. The aim of this article is to delineate all specific steps of TA-AVI, with a

particular focus on patient screening and the surgical technique.

Technique

Patient Screening and Selection

Patients with symptomatic, severe aortic stenosis and high-surgical risk should be considered suitable candidates [4, 5]. High-surgical risk can be defined as a logistic EuroScore calculated risk of mortality $\geq 15\%$, the Society of Thoracic Surgeons' score risk of mortality $\geq 10\%$, or presence of other comorbidities rendering conventional aortic valve surgery difficult, such as a porcelain aorta, previous cardiac surgery with presence of patent grafts, or severe adhesions, previous radiation therapy, liver cirrhosis, need to avoid sternotomy due to patient immobilization, or marked patient frailty. Risk assessment should be performed individually for each patient with the recognition that risk scoring systems are helpful but not completely comprehensive.

Patient screening includes standard preoperative evaluation, particularly echocardiography to exclude other

Accepted for publication August 6, 2008.

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Drs Dewey, Mohr, Mack, and Becht disclose that they have a financial relationship with Edwards Lifesciences Inc.

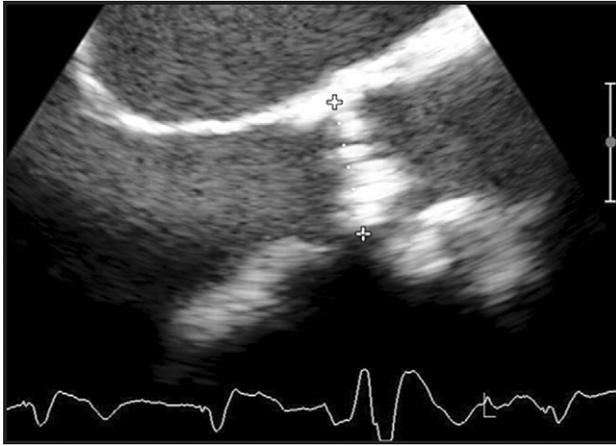


Fig 1. Transesophageal echocardiographic measurement of aortic annulus diameter using the long axis view.

significant lesions requiring intervention. Concomitant mitral regurgitation is frequently present in elderly patients with severe aortic stenosis, but should not be considered as a contraindication to aortic valve implantation unless it is severe or unless there is structural disease of the mitral valve leaflets. Carotid ultrasound should be performed to exclude significant carotid stenosis, and cardiac catheterization should be performed to rule out significant coronary artery disease. In the presence of relevant coronary artery disease, options include high-risk, conventional combined surgery or preoperative coronary stent placement followed by TA-AVI or combined minimally invasive direct coronary artery bypass plus TA-AVI, depending on the individual situation.

Delineation of the aortic root geometry is essential before performing TA-AVI. Transesophageal echocardiography (TEE) is the most reliable tool to measure the diameter of the aortic root (long-axis view), as well as to evaluate the amount and pattern of calcification of the native aortic valve cusps (short-axis view). The diameter

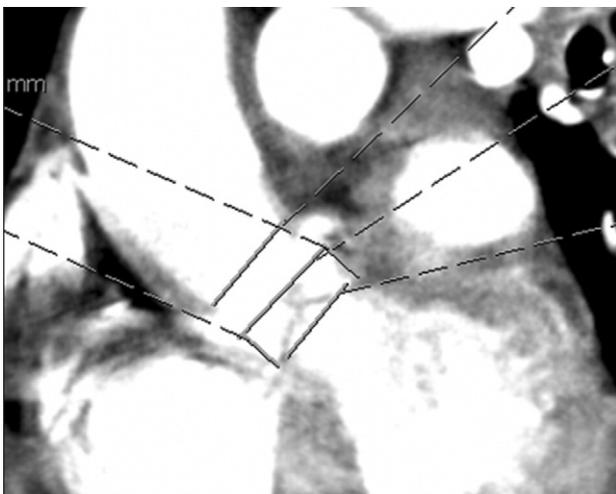


Fig 2. Computerized tomographic imaging of aortic root dimensions.

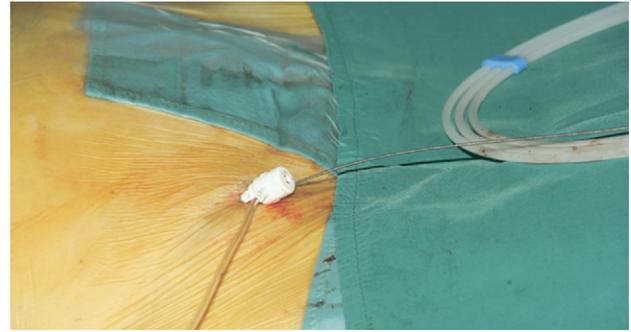


Fig 3. Femoral arterial 6-French sheath and venous guidewire: the "safety net."

of the aortic annulus is measured, including all cusp calcifications, at mid-systole from the insertion of the right coronary cusp at the junction between interventricular septum, aortic annulus, and aortic root, and the insertion of the noncoronary cusp just opposite the junction between the anterior mitral leaflet, aortic annulus, and aortic root (Fig 1). Multiple measurements (at least three) with midline imaging of the aortic root should be performed. Valve size selection, with approximately 10% oversizing, is based on these measurements. That is, a patient with an aortic annulus diameter ≤ 21 mm receives a 23-mm prosthesis, and a patient with an aortic annulus diameter between 22 mm and 24 mm receives a 26-mm prosthesis. A larger 29-mm valve is currently under development that will allow patients with an annular diameter of up to 27 mm to be treated in the near future. Some oversizing is essential to avoid severe paravalvular leakage. However, in presence of a rigid aortic root, too much oversizing should be avoided. There is limited experience with three-dimensional echocardiography, but it is not yet clear whether additional significant information is gained with this technique.

Aortic root dimensions may also be measured during initial cardiac catheterization, but this method is not as sensitive as TEE. Computerized tomography is another method of determining the width of the aortic annulus and it has the added ability of measuring the distance from the aortic annulus to the coronary ostia (Fig 2).

Although the right coronary orifice is usually higher than the left and therefore not at risk of obstruction, the inferior aspect of the left coronary orifice should be 10 to 12 mm from the aortic annulus, especially if heavy eccentric calcification is present in the left cusp. If such a situation is present, consideration can be given to placement of a guidewire in the left coronary artery prior to valve deployment.

Procedure Room and Equipment

The TA-AVI should ideally be performed in a hybrid operating room that includes optimal imaging with a high-quality fluoroscopic system equivalent to that of a cardiac catheterization laboratory with a large image intensifier and immediate replay capability. If such a room is not available, it is advisable to convert a large

cardiac catheterization room into an operative setting than vice versa, since imaging quality is the most crucial factor for these procedures. Optimally, the imaging arm should come from the right side of the patient to allow maximal access to the left side for the surgical team. Placement of monitors on both sides of the patient, including a slave monitor on the right side allows optimal visualization for the whole team. Expertise in TEE is crucial (both for determination of valve positioning and evaluation of post-deployment ventricular function, and possibly for paravalvular leaks). Cardiopulmonary bypass (CPB) is available as a standby during all procedures. Ancillary personnel present should include those with expertise in catheterization equipment, a surgical scrub team, and a perfusionist. Standard operative conditions (including laminar air flow) are strongly recommended to assure adequate sterility. Future advanced imaging modalities may include online three-dimensional TEE and online Dyna-CT (Siemens, Munich, Germany), providing additional three-dimensional visualization of aortic root anatomy and dimensions.

Surgical Technique

A dedicated team of cardiac surgeons, cardiologists, and anesthesiologists should perform the procedure. The merge of skill sets from all such specialists should lead to an optimal outcome for high-risk patients. Team training should be performed before the first procedure is carried out, consisting of didactic teaching of the different operative steps, as well as bench and simulator training on the application of the catheter system. A visit to an experienced center to view an actual implantation is the next step. Finally, the first procedures should be performed by the trained team together with an experienced proctor. It is helpful for the team to practice in multiple “dry runs” so that the team choreography can be determined and

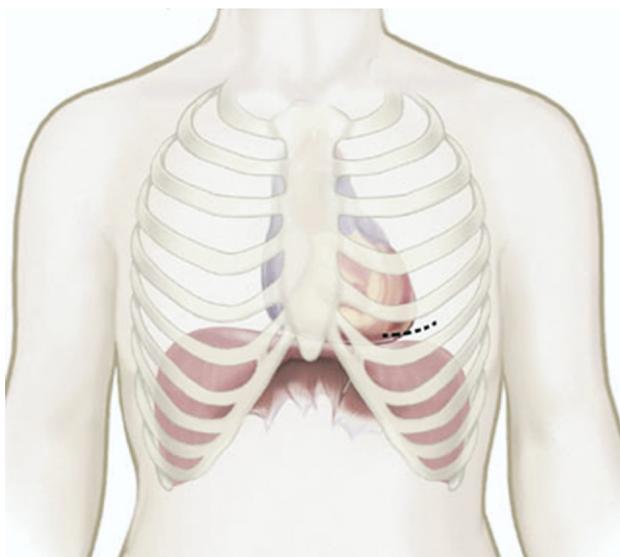


Fig 4. Anterolateral mini-thoracotomy in the fifth or sixth intercostal space.

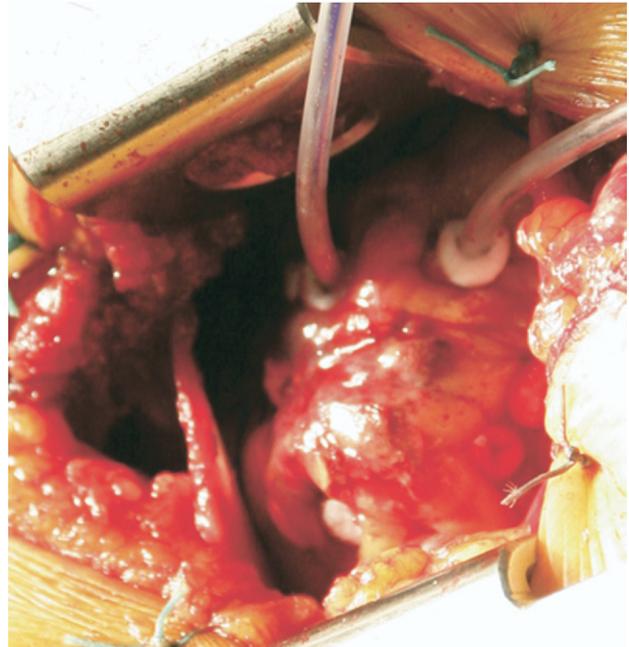


Fig 5. Exposure of the left ventricular apex with Teflon-reinforced pursestring sutures (Ethicon Inc, Somerville, NJ).

optimized, so that a designated role for each team member can be assigned. It should also be clear who will be the “captain of the ship,” so that the procedures proceed in an orderly manner, particularly since so many team members from different backgrounds will be present. Although most procedures proceed without major problems, plans should always be made for a worst case scenario and contingencies should be put in place for all serious complications.

Femoral Access or “Safety Net”

Insertion of a femoral venous wire and an arterial 6-French sheath is strongly recommended to enable rapid cannulation for CPB using the Seldinger technique, if required (Fig 3). If the team is not experienced with percutaneous cannulation for CPB, then consideration should be given to fully expose the femoral vessels. In the presence of kinking of the iliac vessels or excessive tortuosity, a guidewire and sheath positioning under TEE and fluoroscopic guidance may be helpful. It should be determined prior to the procedure by catheterization or computed tomographic evaluation which side will provide the most expeditious and safe access for arterial cannulation, should the necessity of instituting CPB arise. Alternatively, axillary arterial access would be feasible.

A pigtail catheter is also positioned in the aortic root just at the level of the aortic annulus for angiographic visualization and for “landmarking” of the aortic valve. Heparin (100 IU/kg, intravenously) should be given after femoral guidewire and sheath implantation.

Transapical Access

A left anterolateral mini-thoracotomy is placed in the fifth or possibly sixth intercostal space (Fig 4). Use of a

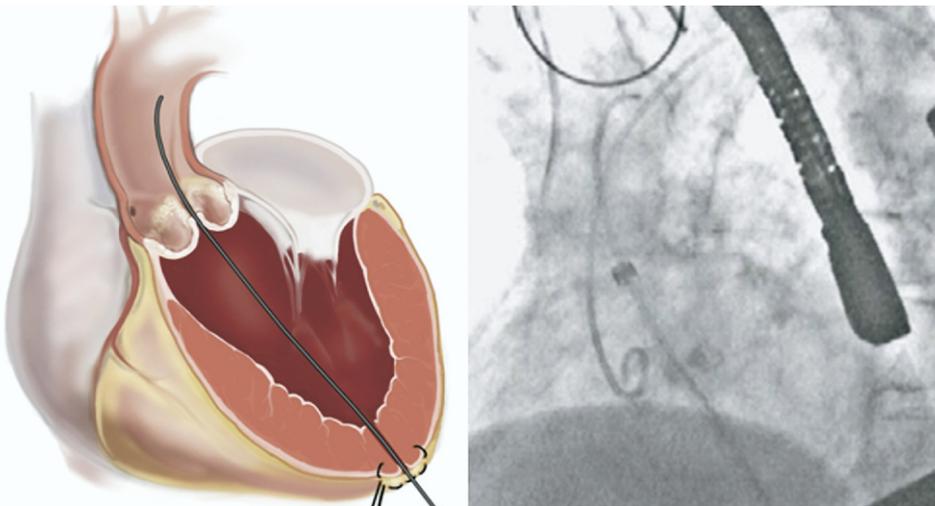


Fig 6. Apical wire insertion, schematic view (left) and fluoroscopic imaging (right).

soft tissue retractor can optimize exposure and minimize rib spreading. The apex of the left ventricle may occasionally be palpated prior to skin incision. Evaluation of a preoperative CT scan addressing the relationship of the apex to the chest wall can help with the positioning of the incision. Straight access to the apex should be achieved. If the apex is not visualized, then the next intercostal space should be opened through the same skin incision. In general, it is better for the incision to be a bit low rather than too high, since the apex can be distracted downward with pericardial traction sutures. The pericardium is opened longitudinally and stay sutures allow for good exposure of the apex. The position of the left anterior descending coronary artery should be confirmed and noted. An epicardial pacing wire is placed and tested for pacemaker capture. Two apical pursestring sutures (Prolene 2-0, large needle with 5 interrupted Teflon pledgets; Ethicon Inc, Somerville, NJ) are placed with sufficiently deep bites in the myocardium (approximately 3 to 5 mm, but not penetrating into the left ventricular cavity), close to the apex and lateral to the left anterior

descending coronary artery (Fig 5). Care should be taken to be sure adequate bites are taken of the muscle and not just the epicardial fat. Placement of the sutures in the bare spot just above the apex on the anterior wall can achieve this more reliably.

Fluoroscopy

Fluoroscopy is positioned to visualize the aortic root and the aortic annulus in a perpendicular angle. All three aortic sinuses and aortic valve cusps should be in one plane. This is usually achieved using an left anterior oblique of $\sim 10^\circ$ and cranial $\sim 10^\circ$ position. It is important to spend sufficient time ascertaining this plane so that parallax does not occur and so that proper valve positioning is achieved. Further adjustment can be performed once contrast dye is given. Perpendicular fluoroscopic imaging can also be assessed later on by observing the crimped valve, once it is in position. The whole circumference of the stent should be in one line at its upper and lower margin. In addition, a maximal distance

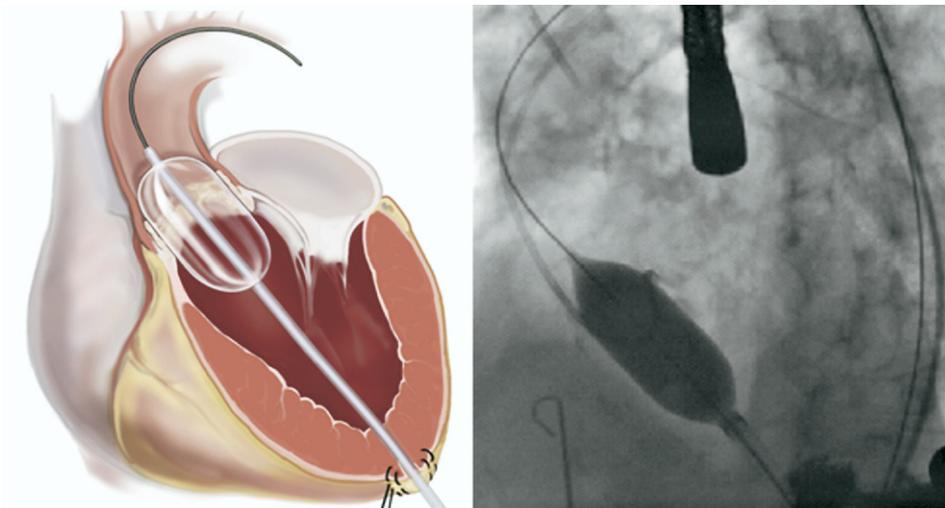


Fig 7. Balloon dilation of the aortic valve, schematic view (left) and fluoroscopic imaging (right).

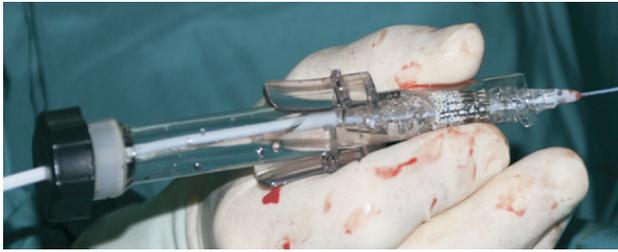


Fig 8. Edwards Sapien prosthesis (Edwards Lifesciences, Irvine, CA) crimped on a balloon catheter and inserted in the loader. Valve orientation, with the white skirt and green suture line at the lower aspect of the prosthesis, must be verified at this step of the procedure.

should be seen between the two radiopaque markers on the balloon catheter.

Hemodynamic stability of the patient is important before proceeding with valve implantation. Volume and low-dose inotropes should be administered if necessary to keep the mean blood pressure greater than 80 mm Hg. All further steps are performed under fluoroscopic control with additional TEE guidance.

Apical Wire Placement

The apex is punctured with a needle, and a soft guidewire is inserted antegrade across the stenotic aortic valve followed by a 14-French (30-cm long) soft-tip sheath that is placed across the aortic valve. A stiff guidewire (Amplatz super stiff, 260 cm; Boston Scientific, Natick, MA) is positioned across the aortic arch and into the descending aorta with the help of a right Judkins catheter (Cordis, Johnson & Johnson, Norderstedt, Germany; Fig 6).

Balloon Valvuloplasty

A 20 mm × 4 cm valvuloplasty (Zmed) balloon (filled with 1:4 diluted contrast) is placed in the aortic valve, and the tip of the 14-French sheath is retrieved into the left ventricle. Balloon valvuloplasty is performed during rapid ventricular pacing (RVP). The RVP is “effective” once there is no significant pulse pressure, indicating a

temporary cessation of left ventricular ejection. The number of times RVP is used should be minimized, because hemodynamic deterioration can occur with repeated RVP, especially in patients with concomitant coronary artery disease or depressed left ventricular function. However, mean arterial pressure should be kept above 60 mm Hg during RVP to avoid hemodynamic deterioration. The RVP is performed at a rate between 170/min and 220/min. Optimal team communication and coordination is required throughout these steps (Fig 7).

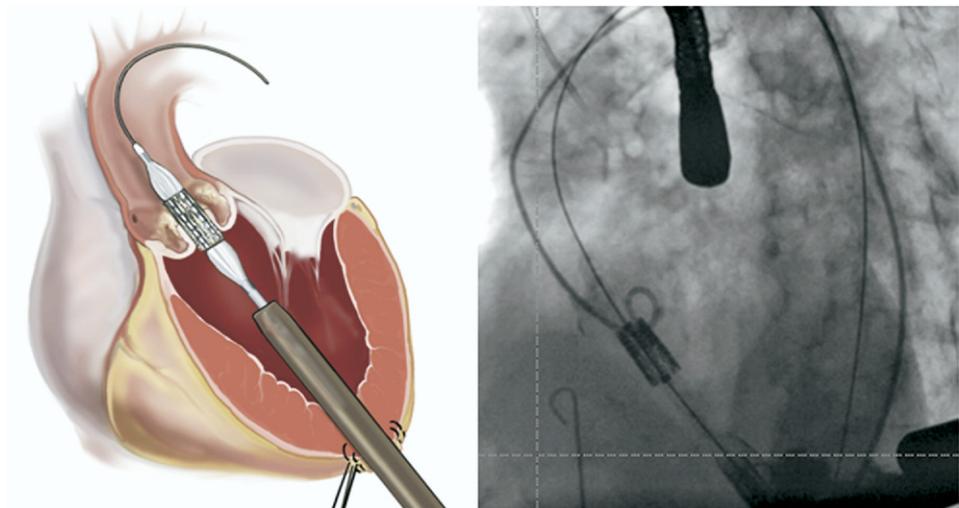
Additional root angiography may be useful during balloon dilatation to visualize the insertion of the coronary arteries. Cessation of ventilation during these periods can be used to minimize valve movement and variation. Balloon valvuloplasty can be considered as a test (“rehearsal”) for actual valve implantation, allowing the team to observe the position of native aortic valve cusps and calcifications, as well as the antegrade or retrograde “slippage” of the balloon during its inflation.

Transapical Sheath Insertion

The balloon catheter is thereafter retrieved together with the 14-French sheath, leaving only the super stiff guidewire in position. The apex is carefully secured with the index finger. The 26-French transapical delivery sheath is subsequently inserted, usually in a blunt fashion. Optimal sheath position will be 4 to 5 cm below the aortic annulus, as visualized fluoroscopically, whereas the external markers remain between 5 and 6 cm in relation to the patient’s epicardium. The introducer is retrieved. The delivery sheath should be kept stable in position and the pursestring sutures may be slightly snared.

During insertion of the sheath, the valve should be simultaneously crimped and positioned in the loader. Valve orientation should be checked before inserting the super stiff guidewire in the delivery catheter and attaching the loader with the sheath. After slight advancement of the catheter, the air can be removed from the loader and the black screw should be slightly closed (Fig 8). Another alternative is placement of the

Fig 9. Valve positioning, schematic view (left) and fluoroscopic imaging (right).



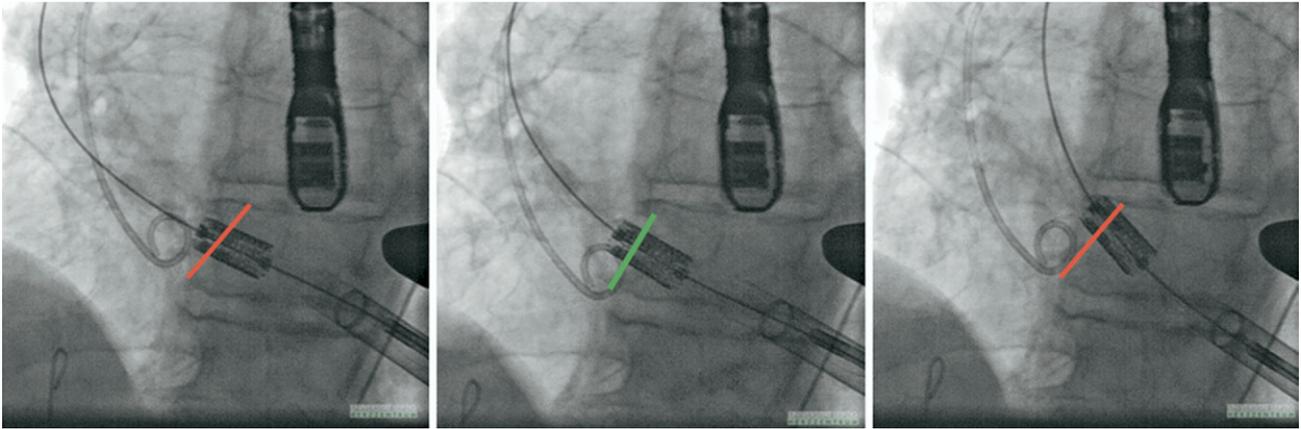


Fig 10. Valve positioning: (middle) correct position perpendicular to the aortic annulus, (left) rightward oblique position due to slack of the wire, and (right) leftward oblique position due to a tight wire.

delivery sheath before the balloon valvuloplasty so that the time between valvuloplasty and valve placement is minimized. This can be helpful if the patient undergoes hemodynamic deterioration after valvuloplasty due to aortic insufficiency.

Valve Positioning

Exact valve positioning is the most critical step during transcatheter aortic valve implantation. The valve is introduced into the annulus and the pusher is retrieved back into the delivery sheath. If the pusher is not pulled back several centimeters prior to valve deployment, subsequent balloon expansion will be impeded and the valve will be pushed obliquely forward. Proper valve positioning is performed under angiographic guidance with supplemental echocardiographic confirmation. We aim at implanting one-third to one-half of the stent above the mid-level of the aortic annulus. Delineation of the annular plane can be achieved by watching cusp calcification and the position of the inserted pigtail catheter, which should be located at the bottom of the right or noncoro-

nary sinus. Once in proper position, continuous, online fluoroscopic imaging should be performed until valve implantation. Slight axial movement should be anticipated and counteracted. An extra episode of RVP may be required to confirm optimal positioning (Fig 9).

There are several key aspects that should be considered during valve positioning: (1) The valve should be oriented coaxial with the long axis of the ascending aorta and just perpendicular to the aortic annulus. Such a position can be reached either in the middle of the aortic annulus or more laterally. Any oblique position may lead to unforeseeable valve misplacement. Correction of oblique positioning can usually be performed with the sheath and the wire by pushing the wire slightly inward, thereby producing slack, which leads to a more rightward position in the annulus, and the wire will move to the convex side of the ascending aorta. On the contrary, pulling back on the wire, thereby tightening it, leads to a more leftward position of the valve in the aortic annulus and the wire will move to the concave part of the ascending aorta (Fig 10). (2) The valve should be inserted

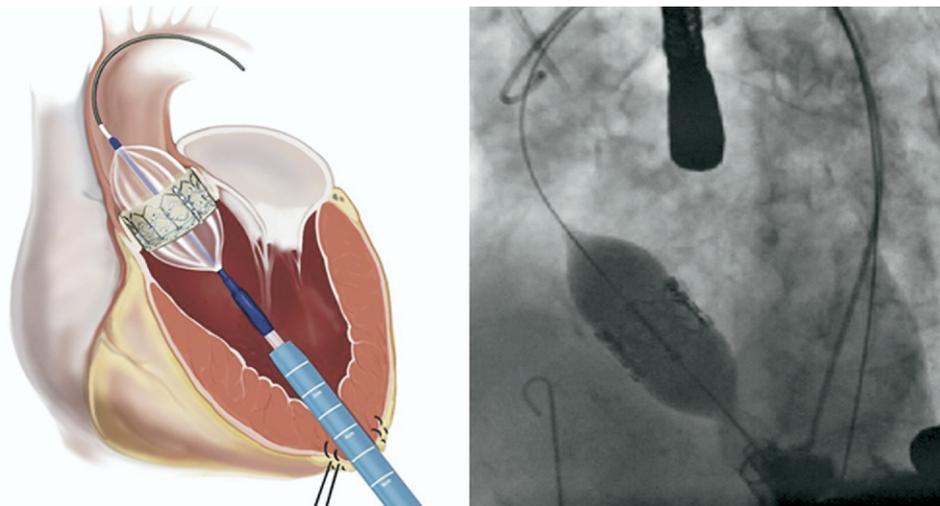
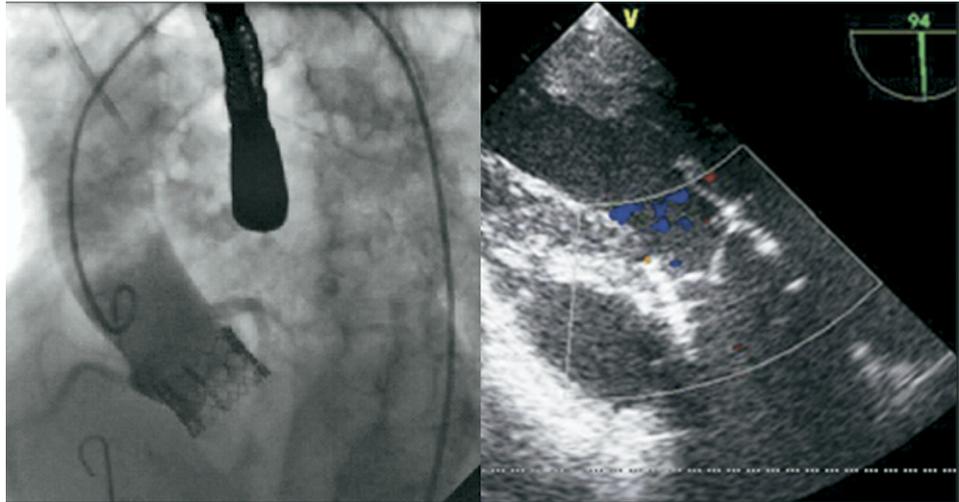


Fig 11. Valve implantation, schematic view (left) and fluoroscopic imaging (right).

Fig 12. Final assessment after transapical aortic valve implantation, fluoroscopic imaging (left) and echocardiographic control (right).



within the annular calcification for the entire circumference. (3) Dilatation of the balloon may occur in an even or in an uneven fashion. Care should be taken in patients with a calcified aortic root and narrow sinotubular junction in which restriction of balloon inflation may occur, resulting in displacement of the valve downward toward the ventricle. In most instances, the valve opens in a slightly uneven manner, usually opening at the distal end first. Gradual inflation may allow for minimal corrections in valve positioning before it achieves its final open state.

Valve Implantation

Valve implantation is performed under repeat RVP and with instantaneous balloon inflation (Fig 11). After successful dilatation and deflation, RVP is stopped, and the balloon is retrieved. Care should be taken to completely deflate the balloon before RVP is stopped. The heart usually recovers within a few seconds. The need for external defibrillation is very infrequent, although external defibrillator pads should be in place prior to patient positioning. To further improve hemodynamic function, some volume loading and possibly inotropic support may be required. Keeping the mean arterial pressure above 80 mm Hg immediately after deployment is crucial, both to optimize valve leaflet closure, in which valve leaflets are open during deployment, and to hasten hemodynamic recovery.

Valve function is assessed using TEE and angiography (Fig 12). There may be central incompetence if the guidewire is still in position. However, the wire is usually left in place until a decision is made regarding the need for repeat balloon dilation.

Repeat dilation is performed in the presence of moderate (2+) paravalvular leak, and it depends on the amount of primary valve dilatation (ie, how fully expanded the valve appears during fluoroscopy). Patient related factors (ie, especially the overall risk profile, amount of calcification, and possible presence of a porcelain aorta) should all be considered before proceeding with repeat dilation. Repeat dilation is performed during another episode of RVP with balloon filling of 1 to 2 mL

more than previously used. A small, signature central leak for pericardial valves is often present, and repeat dilation should not be performed for this reason.

Chest Wall Closure

After valve implantation, the apical sheath and guidewire are simultaneously retrieved. The apex is securely closed using the previously placed two pursestring sutures. Additional sutures may be required (usually with Teflon reinforcement; Ethicon Inc) to achieve complete hemostasis. A final shot of contrast is given into the aortic root to confirm valve function once the guidewire has been removed. Protamine is then administered in a standard dose.

The pericardium is slightly closed to additionally cover the apex. A pleural chest tube or soft drain is inserted. Once all bleeding is controlled and a long-acting local anesthetic is injected in the intercostals spaces, the chest wall and incision are closed in a routine fashion. Depending on local practice, the patient can be immediately extubated in the operating room or shortly thereafter upon transfer to the intensive care or post-anesthetic care unit in the majority of cases.

Clinical Experience

Pitfalls

The TA-AVI is a minimally invasive off-pump procedure that usually proceeds in a straightforward fashion. However, unpredictable events with serious hemodynamic consequences can occur at any time.

Hemodynamic compromise may occur after balloon dilation or after valve insertion, which may require immediate conversion from the off-pump to the on-pump technique. Cannulation for CPB can usually be safely accomplished using the existing femoral access. Further diagnostic (ie, valve and coronary function) and therapeutic interventions (ie, repeat valve dilation, percutaneous transluminal coronary angiography, and so forth) can then be performed.

Details on the optimal straight alignment between the apical sheath, the super stiff guidewire and the aorta have been previously mentioned. Repositioning may be required in case of an oblique angle or if the wire is accidentally caught in the mitral valve apparatus. The use of TEE is helpful for diagnosing this latter problem.

Paravalvular leak is usually minimal when using moderate oversizing of the implanted valves. It has been infrequently necessary to perform post-dilatation of the valve prosthesis because of a paravalvular leak.

Fortunately, coronary obstruction is a rare complication of this procedure. Additional coronary artery bypass grafting or percutaneous transluminal coronary angiography plus stent implantation are useful therapeutic options, depending on the severity of obstruction and the individual situation.

Severe valve dysfunction is uncommon, but it can occur either from intrinsic prosthetic valve leaflet dysfunction or low placement of the stented valve, resulting in overhang of the native leaflet tissue and subsequent insufficient back pressure to close all of the leaflets during diastole. This problem may be solved by implanting a second valve (partially) inside the first one (“valve in a valve” implantation). Valve embolization requires conversion to a conventional surgical technique.

Excessive bleeding from the apex is rare after the transapical approach. If it occurs, additional Teflon-reinforced sutures should be used. Arterial blood pressure should be lowered during pursestring closure.

Tear or rupture of the aortic root has been infrequently observed and requires conversion to a conventional aortic valve replacement with repair of the tear or a complete root replacement operation.

Excessive motion of the balloon during inflation may occur due to several factors: axial motion of the heart (usually in patients with a good ejection fraction), a small sinotubular junction leading to valvular “downshift,” or a prosthetic mitral valve leading to an “upshift.” These movements of the balloon should be carefully watched for during balloon valvuloplasty.

Comment

In conclusion, the TA-AVI technique is new and used as minimally invasive off-pump procedure that has been successfully introduced into clinical practice. Good results have been proven in elderly high-risk patients [1–3]. Pivotal randomized clinical trials are currently in progress.

There are several positive aspects with regard to TA-AVI. It is a truly minimally invasive, off-pump technique; therefore it eliminates the need for cardioplegia or CPB in the majority of patients. Antegrade direct aortic valve implantation is associated with minimal manipulation of the ascending aorta and aortic arch; thus, it is a low-stroke risk when compared with transfemoral implantation. The technique is relatively simple to learn. Access is not an issue, and therefore the size of the delivery system is not relevant. Positioning of the valve can be performed more precisely than for a transfemoral approach, allowing for safe implantation. Most patients, even in the

presence of severe peripheral vascular disease, can undergo this procedure. The transapical access, however, requires a mini-thoracotomy that may be a slight disadvantage, especially in patients with severe chronic obstructive pulmonary disease and supplemental oxygen dependency, and in those patients with significant debility or frailty. However, totally endoscopic approaches may be feasible in the future.

The TA-AVI technique should ideally be performed in a hybrid operating room by a dedicated team of cardiac surgeons, cardiologists, and anesthesiologists. The merging of specific skill sets from all of these specialists will lead to an optimal outcome for high-risk patients. The TA-AVI technique is evolving; however, it will continue to undergo several modifications, including the development of newer devices. Close monitoring of clinical outcomes and results of ongoing clinical trials will be crucial for determining the optimal future patient population for these procedures.

Disclosures and Freedom of Investigation

All authors had the freedom from outside interests in controlling the design of the study, acquisition of data, collection, analysis, and interpretation of data, and disclosing all results. During the past 12 months there was no financial conflict of interest with any commercial entity or competitor whose products are featured, described, reviewed, evaluated, or compared in the article for the authors Walther, Borger, Kempfert, Linke, Falk, and Schuler. The authors Dewey, Mohr and Mack are consultants to Edwards Lifesciences Inc. The author Becht is an employee of Edwards Lifesciences Inc. None of the authors has received any financial compensation for this publication.

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