

Transapical Aortic Valve Implantation

ROBERTO BATTELLINI, THOMAS WALTHER, JÖRG KEMPFERT, MICHAEL BORGER, STEFAN SCHULER, AXEL LINKE, FRIEDRICH MOHR

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Address for reprints:

Herzzentrum Leipzig
Struempellstrasse 39, 04289
Leipzig, Germany
e-mail:
battr@medizin.uni-leipzig.de

SUMMARY

Almost 30% of aortic valve replacements are due to aortic stenosis; therefore, certain groups of patients present high operative risk. This article describes transapical aortic valve implantation, a minimally invasive off-pump procedure. This technique represents a new alternative for patients with advanced age and increased operative risk, severe calcifications of the aorta, or previous coronary revascularization. Delineation of the aortic root geometry is essential. Transesophageal echocardiography is the most reliable tool to measure the diameter of the aortic root. 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*. Cardiopulmonary bypass should be available as a stand-by during all the procedure, which consists of an anterolateral mini-thoracotomy for direct antegrade surgical access through the apex of the left ventricle; then a catheter is inserted and placed in the aortic position under fluoroscopic guidance. Balloon valvuloplasty is performed thereafter, followed by transapical sheath insertion and prosthetic valve positioning. Exact valve positioning is the most critical step. The use of DYNA CT imaging software has improved the perspectives for the definite development of this technique. From February 2006 to December 2008, 192 aortic valves have been implanted transapically; mean age of patients was 82.5 ± 5.7 years. Mortality 30 days after the procedure was 8.9% and 12.8% at long-term follow-up (256 ± 213 days). Implantations are optimally performed in a hybrid operating room by an experienced team of cardiac surgeons, cardiologists, and anesthesiologists.

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Key words >

Aortic Valve - Transapical Aortic Valve Implantation - Minimally Aortic Valve Surgery

Abbreviations >

CPB Cardiopulmonary bypass

TEE Transesophageal echocardiography

RVP Rapid ventricular pacing

AVR Aortic valve replacement

TA-AVI Transapical aortic valve implantation

BACKGROUND

Recent publications have communicated that approximately 30% of patients with severe aortic stenosis are rejected from conventional aortic valve replacement (AVR) because of high-risk profiles. (1, 2)

Two minimally invasive procedures that might help to solve this issue are currently under clinical research. These techniques are not based on the resection and replacement of the native valve; conversely, they use aortic balloon valvuloplasty with aortic valve implantation, a procedure initiated by Alain Cribier in 2002. (3)

This article describes transapical implantation of the aortic valve (TA-AVI), a minimally invasive off-pump procedure. Recent studies (4-6) have evaluated the feasibility of this procedure, and the European conformity CE mark of approval for TA-AVI of the Sapien valve (Edwards Lifesciences Inc, Irvine, CA) was granted in January 2008.

INDICATIONS

Transapical implantation of the aortic valve is particularly indicated in elderly patients with high surgical risk, with a heavily calcified "porcelain" aorta, or with previous coronary surgery and/or a patent mammary artery graft close to the sternum. (4-8) High operative risk was defined by a logistic Euroscore > 15% or STS score > 10%, taking into account that risk scoring systems are helpful but not completely comprehensive. Patients with previous radiation therapy, liver cirrhosis, need to avoid sternotomy, pronounced frailty or with calcification of aortic valve bioprostheses (valve-in-a-valve concept) are also candidates for TA-AVI. (7, 8)

PREOPERATIVE ASSESSMENT

Doppler echocardiography rules out significant lesions requiring intervention, such as mitral regurgitation,

which should not be considered as a contraindication to aortic valve implantation unless it is severe. Coronary angiography should be performed to exclude coronary artery disease, to indicate stent implant before TA-AVI or MIDCAB followed by TA-AVI using the same minimally invasive sternotomy, or to decide a conventional surgery.

Delineation of the aortic annulus geometry is essential: transesophageal echocardiography (TEE) is the most reliable tool to measure the diameter of the aortic root (long axis view) (Figure 1 A) as well as the severity and the type of calcification of the valves (short axis view). The aortic annulus is measured at least three times and valve size is selected, with approximately 10% oversizing to avoid paravalvular leakage. For example, a patient with an aortic annulus diameter < 21mm receives a 23-mm prosthesis, and a patient with an aortic annulus diameter between 22 mm and 24 mm receives a 26-mm prosthesis. Valve prostheses of greater size are under development and are not available yet.

In presence of a rigid aortic root, too much oversizing should be avoided. We believe that cardiac catheterization does not provide such an accurate measurement of the aortic diameter. 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 (Figure 1 B). The right coronary orifice is usually higher than the left and has less risk of calcification and obstruction. A guide wire should be used before valve implantation in case of heavy eccentric calcification is present in the left cusp.

TECHNIQUE

A dedicated team of cardiac surgeons, cardiologists, and anesthesiologists should perform the procedure; one of the members should be in charge of decision-making in case complications develop. The procedure is performed in an hybrid catheterization laboratory / operating room setting equipped with fluoroscopy and transesophageal echocardiography. The quality of images is essential for the procedure. The imaging arm should be placed at the patient's right side. Slave monitors should be placed to allow optimal visualization for the whole team.

Cardiopulmonary bypass should be available as a stand-by during all the procedure.

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 (Figure 1 C). A pigtail catheter is 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.

Thoracotomy

After the apex of the left ventricle is identified by palpation, an anterolateral minithoracotomy is performed in the 5th or 6th intercostal spaces to expose the left ventricular apex (Figure 2 A). In general, it is better for the incision to be a bit low rather than too high. The pericardium is opened longitudinally and stay sutures are placed. An epicardial pacing wire is placed in the ventricle for rapid pacing. Two apical pursestring sutures with Prolene 2-0, large needle with 5 interrupted Teflon pledgets 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 (Figure 2 A).

Fluoroscopy

Fluoroscopy is positioned to visualize the aortic root and the aortic annulus in a perpendicular angle. The aortic sinuses and aortic valve cusps should be in one plane; this is usually achieved using a left anterior oblique of 10° and cranial 10° position. This is a key step to avoid parallax in order to achieve the proper valve positioning. Further adjustment can be performed once contrast dye is given, especially by observing the crimped valve. Hemodynamic stability of the patient is essential before proceeding with valve implantation and mean blood pressure should remain greater than 80 mm Hg.

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. The

Fig. 1. Imaging tests and cardiac catheterization.



soft guidewire is withdrawn and a right Judkins catheter (Cordis, Johnson & Johnson, Norderstedt, Germany) is inserted. A stiff guidewire (Amplatz superstiff, 260 cm; Boston Scientific, Natick, MA) is positioned across the aortic arch and into the descending aorta through the Judkins catheter (Figure 2 B).

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) at a rate between 170/min and 220/min (Figure 2 C). Optimal team communication and coordination is required. 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. Mean arterial pressure should be kept above 60 mmHg.

Additional root angiography may be useful during valvuloplasty to visualize the insertion of the coronary arteries. Cessation of ventilation during these periods can be used to minimize valve movement. The balloon catheter is thereafter retrieved together with the 14-French sheath, leaving only the super stiff guidewire in position. Occasionally, a patient may show hemodynamic impairment due to aortic regurgitation.

Transapical Sheath Insertion

The Sapien valve (Edwards Lifesciences Inc, Irvine, CA) the valve is crimped on the balloon, and the orientation of the valve is checked to avoid an inverted implantation (Figure 3 A). The 26-French transapical delivery sheath is subsequently inserted. 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.

Valve Positioning

Exact valve positioning is the most critical step during the whole procedure. The valve is introduced into the annulus and the pusher is retrieved back into the delivery sheath. Proper valve positioning is performed under angiographic and echocardiographic guidance. The aim is 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 non-coronary sinus. (Figure 3 B).

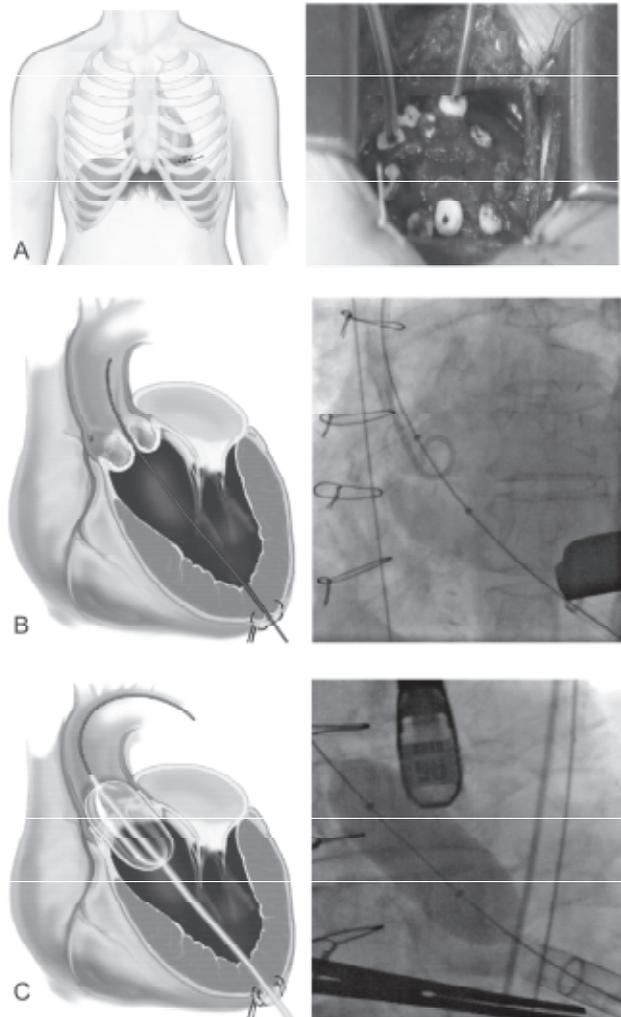


Fig. 2. Exposure of the left ventricular apex.

During positioning, the valve should be oriented coaxial with the long axis of the ascending aorta and perpendicular to the aortic annulus. Any oblique position may lead to unforeseeable valve misplacement (Figure 3 C). The valve should be inserted within the annular calcification for the entire circumference. Gradual balloon inflation may allow for minimal corrections in valve positioning before it achieves its final open state (Figure 3 D).

The use of DYNA CT (Siemens) imaging software allows contrast injections under rapid pacing to prevent immediate wash-out. With the use of rotation angiography (the x-ray tube revolves around the patient rapidly, completing a 360° rotation) the software projects the aorta and the coronary arteries like the image of an airplane landing at night.

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. Transesophageal echocardiography is performed and a final shot of contrast is given to confirm valve function (Figure 4).

Protamine is then administered. The pericardium is slightly closed and a pleural chest tube is inserted. Depending on local practice, the patient can be immediately extubated in the operating room.

Eventual Use of Cardiopulmonary Bypass

Cardiopulmonary bypass (CPB) may be necessary in case of hemodynamic instability which may occur after the valvuloplasty or valve insertion. Cannulation is performed via the femoral access or safety net. Fur-

ther diagnostic and therapeutic interventions (repeat valve dilation, coronary angiography, etc.) can then be performed. Repositioning may be required in case of an oblique angle.

Paravalvular leakage is usually minimal when using moderate oversizing of the implanted valves. It has been infrequently necessary to perform post-dilatation. Coronary calcium obstruction is a rare complication of this procedure which may be treated with stent implantation or coronary artery bypass grafting. If the stented valve is placed in a low position, overhang of the native leaflet tissue may occur with subsequent insufficient back pressure to close all of the leaflets. This problem may be solved by implanting a second valve (valve-in-a-valve implantation).

Excessive bleeding from the apex is rare; however, in other series this has led to complications and even death in absence of instituting CPB. Tear of the aortic root has been infrequently observed and requires conversion to a conventional aortic valve replacement with eventual Bentall-de Bono surgery.

RESULTS FROM THE HERZZENTRUM CARDIOVASCULAR SURGERY CENTER (LEIPZIG)

From February 2006 to December 2008, transapical aortic valve implantation was performed in 192 patients. A total of 133 patients were women, mean age was 82.5 ± 5.7 years, logistic Euroscore was $32\% \pm 16\%$ and STS score was $14\% \pm 9\%$. Mean NYHA functional class was 3.2 ± 0.5 .

Conversion to conventional surgery had to be performed in 5 patients; two of them died, one due to valve dislocation and the other due to ventricular rupture. Of the three patients who survived, one presented coronary occlusion due to calcium crimped by the balloon and underwent coronary revascularization with two grafts; the remaining two patients presented aortic root dissection and were treated with Bentall-de Bono surgery. Cardiopulmonary bypass was used in the first 10 patients by intention (5%) and in 11 additional patients thereafter (6%). A total of 169 patients (89%) were treated completely off-pump.

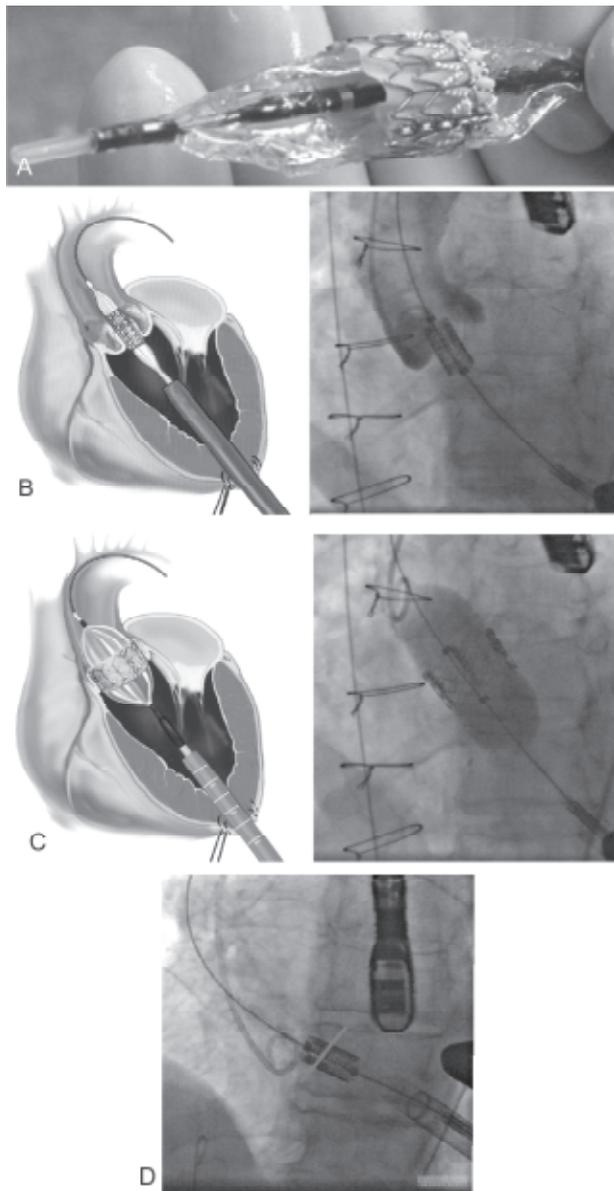


Fig. 3. Balloon insertion.

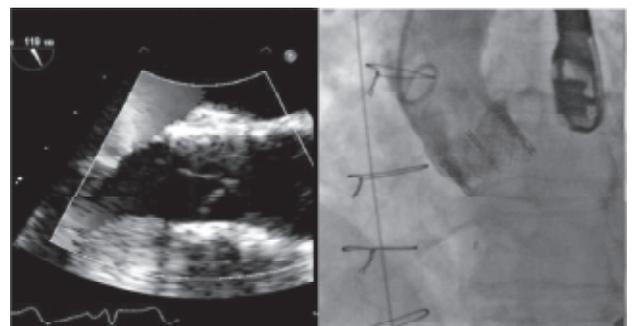


Fig. 4. Valve positioning.

Mortality

Two patients died during conversion to conventional surgery, unresponsive to cardiopulmonary resuscitation; at 30 days, mortality rate was 8.9% (17/190). At a long-term follow-up of 256 ± 213 days (74 patient-years) 21/164 patients died (12.8%).

When comparing the learning curve of the initial 120 patients versus the last 72 patients receiving the CE-approved transapical aortic valve prosthesis, we observed an improvement in 30-day survival: 88% versus 95.6%, respectively. At 6 months, this difference was even more significant: $94\% \pm 3\%$ in the second series versus $73\% \pm 4\%$ in the initial patients. STS scores were similar in both series.

CONCLUSION

Transapical aortic valve implantation technique is new and used as minimally invasive off-pump procedure that has been successfully introduced into clinical practice in elderly high-risk patients.

Compared with transfemoral implantation, antegrade TA-AVI is associated with minimal manipulation of the aorta, with low risk of stroke. Positioning of the valve can be performed more precisely than for a transfemoral approach, and can be used even in the presence of severe peripheral vascular disease. The transapical access, however, requires a mini-thoracotomy that may be a slight disadvantage, especially in patients with severe chronic obstructive pulmonary disease or in those patients with significant frailty.

Endoscopic approaches are under development.

A precise measurement of the valvular annulus and a thorough examination of calcium minimize potential complications.

The TA-AVI technique should ideally be performed in a hybrid operating room by a dedicated team of cardiac surgeons, cardiologists, and anesthesiologists.

SUMMARY

Implantación transapical de la válvula aórtica

El reemplazo valvular aórtico por estenosis es notoriamente alto, hasta un 30% en poblaciones estudiadas, lo cual implica en determinados grupos un riesgo quirúrgico elevado. En este artículo se describe la implantación transapical de la válvula, un procedimiento miniinvasivo y en principio sin circulación extracorpórea. Se indica preferentemente en pacientes ancianos con alto riesgo operatorio, en aquellos con aortas gravemente calcificadas y en otros con revascularizaciones coronarias previas. El estudio de la geo-

metría aórtica es esencial: la ecocardiografía transesofágica da la mejor medida del diámetro de la raíz aórtica y la tomografía computarizada determina exactamente el diámetro del anillo y tiene la posibilidad agregada de medir la distancia desde el anillo a los ostia coronarios. Se debe contar con la posibilidad de circulación extracorpórea en carácter de *stand-by*. Por una pequeña toracotomía anterolateral se accede a la punta del corazón donde se cateteriza el ventrículo hacia la posición aórtica con control radioscópico. La valvuloplastia, la inserción de la vaina transapical y el posicionamiento de la prótesis son las maniobras siguientes. El posicionamiento de la válvula constituye el paso más crítico, pero con esta técnica es más eficaz. En los últimos casos, mediante el *software* denominado DYNA CT, se han logrado mejores perspectivas en un punto crucial para el desarrollo definitivo. Desde febrero de 2006 hasta diciembre 2008 se implantaron 192 válvulas por vía transapical en pacientes con una edad media de $82,5 \pm 5,7$ años. La mortalidad a los 30 días fue del 8,9% y en el seguimiento alejado a 256 ± 213 días fue del 12,8%. Esta técnica debe ser realizada en un quirófano híbrido por un equipo especializado y debidamente entrenado de cirujanos, cardiólogos y anestesiólogos para obtener resultados óptimos.

Palabras clave > Válvula aórtica - Implante valvular aórtico transapical - Cirugía valvular aórtica miniinvasiva

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