Percutaneous Aortic Valve Replacement in High-Risk Patients

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SUMMARY

A significant proportion of patients with severe aortic stenosis (AS) have comorbidities that increase the risk of surgical aortic valve replacement. Percutaneous implantation of aortic valve prosthesis emerges as an alternative in this group of patients. We report two cases of elderly patients with severe aortic stenosis that underwent successful percutaneous implantation of CoreValve aortic valve prostheses; in addition, criteria for patient selection and the technique of the procedure are described.

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Key words > Aortic Valve - Heart Valve Prosthesis - Catheterization – Endovascular

Abbreviations >

AVRS Aortic valve replacement surgery	**AS** Aortic stenosis
LAD Left anterior descending coronary artery	**LV** Left ventricle

BACKGROUND

Severe aortic stenosis (AS) is the most frequent valvular heart disease in the Wertern world and its prevalence increases due to greater population longevity. (1) Patients with symptomatic AS have a poor quality of life and elevated mortality. (2) Hitherto, aortic valve replacement surgery (AVRS) is the only definite therapeutic option capable of improving symptoms and long-term prognosis. (3) However, in patients with increased risk for surgery, up to 30% of patients are declined for surgery. (1) Even more, the presence of contraindications to surgery is associated with reduced survival rates. In this group of patients, percutaneous valvuloplasty emerged as a therapeutic alternative. Yet, as the procedure is associated with high rate of restenosis, it was limited only as a bridge to surgery. (4) Percutaneous aortic valve replacement is an innovative technique that is being incorporated to clinical practice with on growing enthusiasm, particularly in patients with high risk for surgery. (5, 6)

In this article we describe two case reports, the criteria used for patients' selection and the technique used.

CASE 1

An 89-year old woman with a history of multiple hospitalizations due to decompensated heart failure presented with NYHA class III dyspnea. Transthoracic 2D echocardiography, 3D and Doppler echocardiography revealed the presence of significant calcifications in a trileaflet aortic valve with severe stenosis (peak aortic gradient: 69 mm Hg; mean aortic gradient: 40 mm Hg; aortic valve area: 0.6 cm^2) and moderate aortic regurgitation (Figure 1 A-C). Left ventricular ejection fraction was 62% and there was evidence of grade III diastolic dysfunction, characterized by a restrictive mitral filling pattern; systolic pulmonary artery pressure was 52 mm Hg. The aortic valve annulus measured 24 mm and the distance between the aortic annulus and the sinotubular junction was 15 mm (Figure 1 A-C). Coronary angiography showed absence of significant obstructions. EuroScore risk was estimated in 13.6%. The patient was not considered a candidate for surgery due to advanced age. The feasibility of performing a percutaneous aortic valve replacement was determined by several angiographic evaluations (Figure 2 A-B). The patient underwent a successful percutaneous implantation of an aortic valve prosthesis (Figures 3 A-B and 4 A-C) with a peak gradient of 16 mm Hg after the implant and moderate aortic regurgitation. Immediately after, the heart valve prosthesis was dilated with a 25-mm balloon, reducing the degree of aortic regurgitation (Figure 3 C-D). The electrocardiogram performed after the procedure showed preserved AV conduction and a new complete left bundle branch block. During the next 72 hours the patient alternated between normal sinus rhythm and pacemaker rhythm, and a definite pacemaker was implanted thereafter. The postoperative echocardiogram showed the prosthetic valve correctly positioned and a mild aortic regurgitation (Figure 5 A-C). The patient was discharged without major complications in NYHA functional class I.

CASE 2

In this case, a woman aged 90 years presented with NYHA functional class III dyspnea; she had a history of progressive dyspnea during the last 2 years. She was 1.52 m tall, weighted 59 kg, and her body mass index was 26. The operative risk estimated by the EuroScore was 14.6%. The

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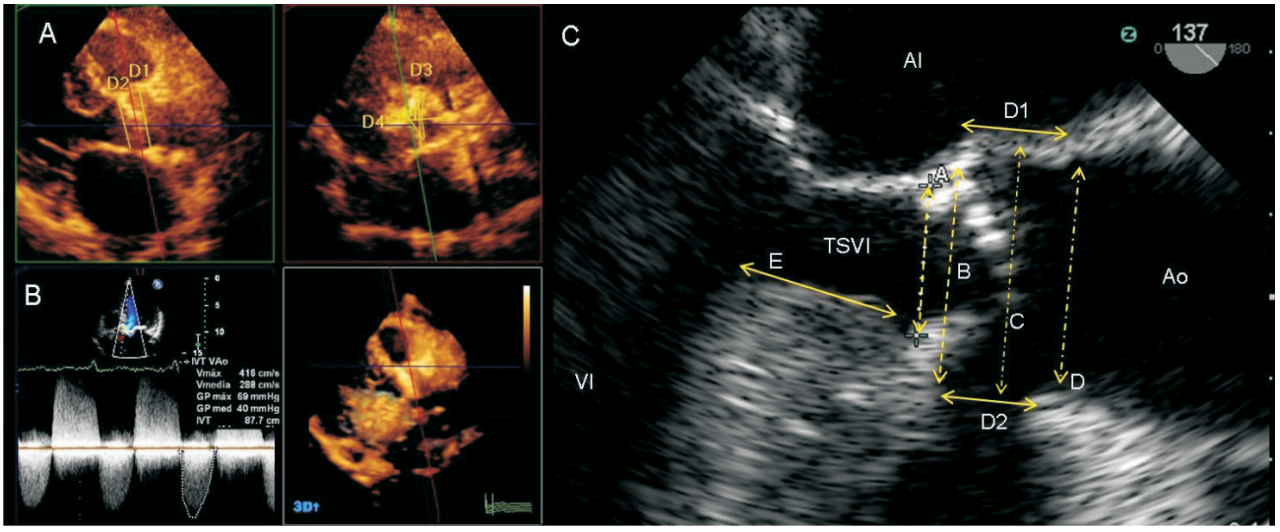

Fig. 1. A. 3D echocardiography. Multiplanar review at the level of the aortic valve. Evaluation of aortic diameters and aortic valve area. **B.** Continuous wave Doppler trace through the aortic valve showing peak and mean gradients of 69 mm Hg and 40 mm Hg, respectively. **C.** TEE. Longitudinal view (137 degrees). See the different pre-procedural measurements. A: LVOT. B: Aortic annulus. C: Valsalva sinus. D: Sinotubular junction. E: Interventricular septum thickness at the level of the aortic valve. D1 and D2: Distance from the aortic annulus to the sinotubular junction. TEE: Transesophageal echocardiogram. TTE: Transthoracic echocardiogram. LA: Left atrium LVOT: LV outflow tract: LV: Left ventricle. Ao: Ascending aorta.

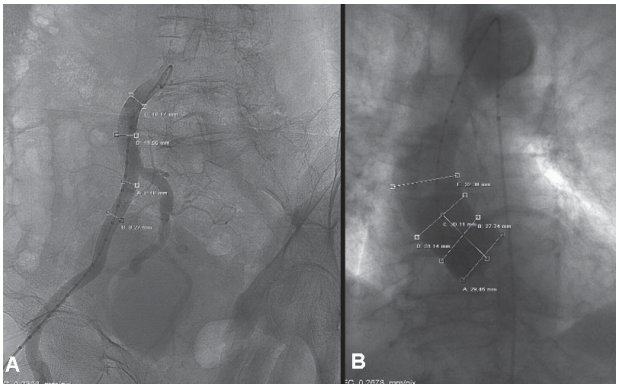

Fig. 2. A. Measurement of the femoral and iliac artery diameters using quantitative angiography. **B.** Measurements of the aorta to assess the feasibility of performing a percutaneous aortic valve replacement.

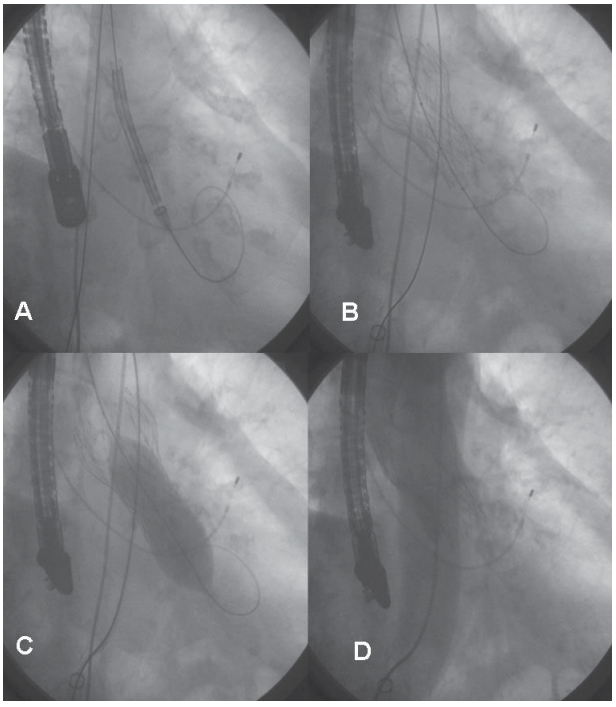

Fig. 3. CoreValve prosthesis positioning (**A**) and expansion (**B**). **C.** Post-dilatation of the prosthesis. **D.** Final result. A mild aortic regurgitation is visible.

echocardiogram showed a calcified trileaflet aortic valve with severe stenosis (peak aortic gradient: 80 mm Hg; mean aortic gradient: 52 mm Hg; aortic valve area: 0.75 cm^2) and mild aortic regurgitation. Left ventricular ejection fraction was 58%. There was a moderate increase in LV filling pressures due to grade II diastolic dysfunction and pulmonary artery systolic pressure was estimated in 56 mm Hg. The aortic valve annulus measured 22 mm and the distance between the aortic annulus and the sinotubular junction was 16 mm. The coronary angiography only showed irregularities in the mid-LAD artery segment.

Percutaneous 26-mm aortic valve prosthesis was successfully implanted, with complete resolution of the transvalvular aortic gradient and moderate aortic regurgitation that was significantly reduced after dilatation with a 25 mm balloon. A definite pacemaker was implanted 24 hours after the procedure due to trifascicular block. The echocardiogram performed before discharge showed that the aortic valve prosthesis was properly placed, the transvalvular gradients were normal and there was a mild aortic regurgitation.

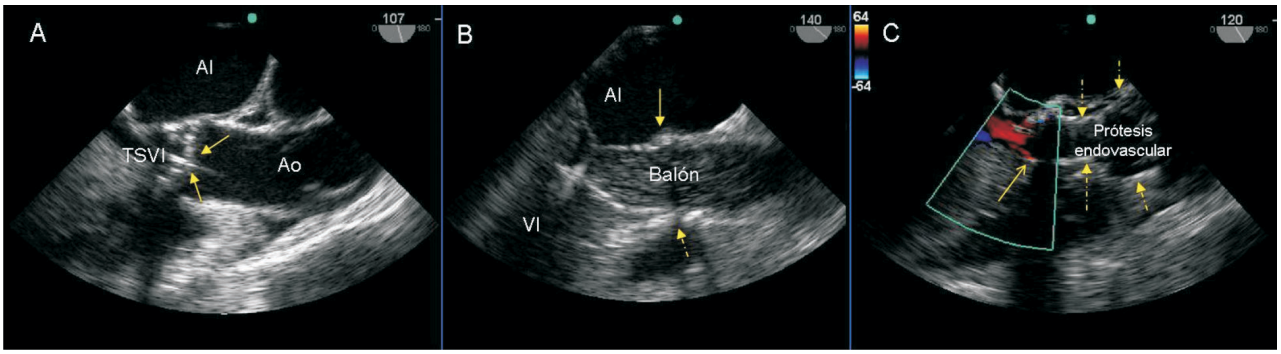

Fig. 4. TEE monitoring during the procedure. **A.** Longitudinal view (107 degrees). The catheter advances across the aortic valve (arrows). **B.** Longitudinal view (140 degrees). The balloon is insufflated. The arrows show the region of the valve annulus. **C.** Longitudinal view (120 degrees). The device is correctly positioned and expanded (dashed arrows). Doppler color image shows the presence of minimal paravalvular leakage (full arrow).

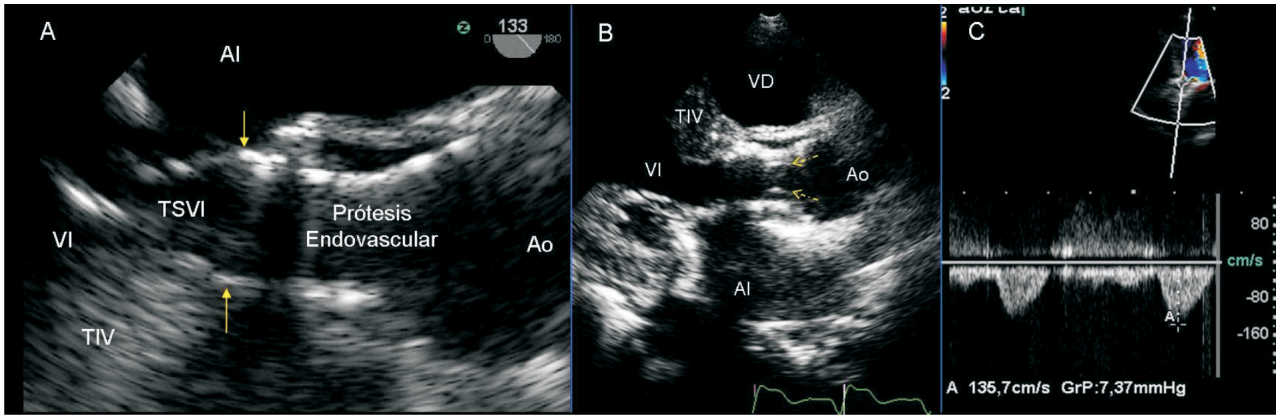

Fig. 5. A. TEE immediately after the procedure. Longitudinal view (133 degrees) showing the valve prosthesis fully expanded and correctly positioned. The arrows mark the proximal border of the prosthesis at the level of the LVOT. **B.** TTE. Endovascular prosthesis in correct position. See the fine valves opened during systole (arrows). **C.** Continuous wave Doppler trace through the aortic valve with a peak gradient of 7 mm Hg.

REQUIREMENTS FOR SELECTION OF PATIENTS FOR SELF-EXPANDING VALVE PROSTHESIS

Patients with the following features are eligible for percutaneous aortic valve implantation: 1) presence of symptomatic AS and high surgical risk; 2) aortic annulus diameter ≥ 20 mm and ≤ 27 mm as measured on echocardiography; 3) distance between the aortic annulus and the sinotubular junction > 14 mm; and, 4) diameter of the ascending aorta 3 cm above the annulus of < 43 mm. Three-dimensional echocardiography with multiplanar review allows direct and correct measuring (Figure 2). (5)

Coronary angiography (either by cardiac catheterization or by multislice computerized tomography) is essential to rule out the presence of coronary artery disease and to assess the diameters of the aortic annulus and ascending aorta at 30 mm from the valve annulus and the distance between the aortic annulus and the origin of the coronary arteries. The angles between the left ventricle and the aortic root and between the aortic arch and the descending aorta can be estimated during coronary angiography in order to evaluate the feasibility of navigation of the device. In addition, it is also useful to determine the degree of tortuosity of the iliac and femoral tree, and the diameters of the femoral, external iliac and common iliac arteries.

DEVICE DESCRIPTION

The CoreValve aortic valve prosthesis (CoreValve Inc, California, USA), consists of a trileaflet bioprosthetic pericardial tissue valve that is mounted and sutured in a self-expanding nitinol stent (Figure 6). The lower portion of the prosthesis that is implanted from the left ventricular outflow tract has high radial force at the level of the valve annulus to expand and exclude the calcified leaflets and to avoid recoil. The middle portion is designed to avoid obstruction of the coronary arteries, and the upper portion is flared to fixate

the stent in the ascending aorta and to provide longitudinal stability. The current profile of the prosthesis is 18 F. The prosthesis is available in two sizes: 26 mm and 29 mm for aortic annulus diameter between 20 and 23 mm and between 23 and 27 mm, respectively.

PROCEDURE DESCRIPTION

The procedure is performed under angiographic, hemodynamic and echocardiographic guidance. Some experienced teams do without the latter. We believe that an echocardiography-guided procedure is useful to evaluate diameters, to monitor the introduction of catheters to prevent possible tears of atherosclerotic plaques in the descending aorta, to help ensure appropriate positioning of the prosthesis and to assess for paravalvular regurgitation. A transient pacemaker is implanted and removed 48 hours later due to potential risks of conduction disturbances and need of definite pacemaker implantation. The femoral artery is the most frequent vascular access used and an 18 F introducer is inserted. Vascular access can be obtained by standard surgical dissection or in a percutaneous fashion with the aid of a vascular pre-closing device. The subclavian artery is an alternative route in case of inadequate femoral access. A pigtail catheter is introduced via the femoral or radial artery in order to measure pressure gradients and, simultaneously, for angiographic control to aid positioning of the CoreValve aortic valve prosthesis.

Once the transvalvular aortic gradient has been measured, a dilatation is performed with a valvuloplasty balloon; the diameter of the balloon is similar to that of the aortic annulus. Then, the device is advanced through the femoral artery and positioned at the level of the valve annulus (Figure 3). The sheath is retracted allowing deployment of the self-expanding prosthesis In case of significant stenosis or paravalvular regurgitation, the prosthetic valve can be dilated with a balloon of a greater diameter.

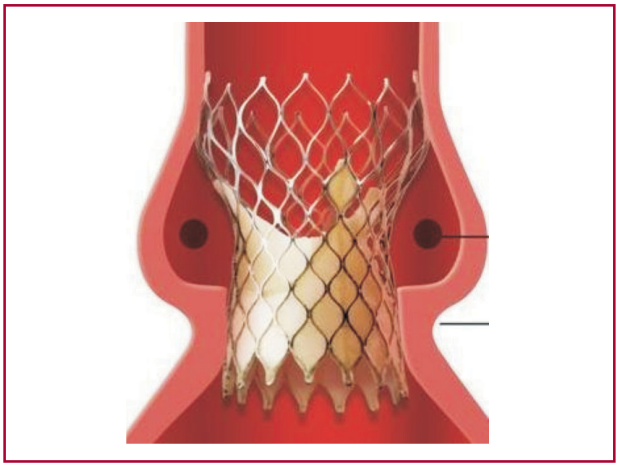

Fig. 6. Diagram of the CoreValve prosthesis positioned at the level of the valve annulus, respecting the coronary ostia.

DISCUSSION

Currently, the presence of multiple comorbid conditions or advanced age is a limitation to AVRS in a great number of patients. (1) So far, two types of prosthetic valves have been implanted (CoreValve and Edwards LifeScience) in approximately 5000 patients, with increasing success. This new technique widens the scope of patients with AS who may benefit from a definite treatment. Specifically, implant of CoreValve prosthesis is associated with high success rate and low rate of complications. (5) The reduction of the profile of this prosthesis from 25 F to 18 F has decreased the incidence of complications, such as temporary or permanent stroke and iliac or femoral trauma. (5) However, in 20% of cases the development of bradyarrhythmias makes it necessary to implant a definite pacemaker. (7) The presence of aortic regurgitation after the implant is generally related to paravalvular leakage usually disappears gradually due to progressive expansion of the prosthesis and to development of perivalvular fibrosis. In some cases a subsequent dilatation reduces the paravalvular leakage. Other complications, such as cardiac tamponade, occlusion of the coronary ostia after the implant, device implantation into the ascending aorta or into the left ventricle, are more frequent in inexperienced centers. These findings emphasize the need of a rigorous training before implementing this technique.

RESUMEN

Reemplazo valvular aórtico percutáneo en pacientes de alto riesgo quirúrgico

Una proporción importante de pacientes con estenosis aórtica (EAo) grave poseen comorbilidades que incrementan el riesgo de la cirugía de reemplazo valvular aórtico. El implante percutáneo de válvula protésica surge como una alternativa en este grupo de pacientes. Se comunican dos casos de pacientes de edad avanzada portadores de EAo grave a los que se les realizó con éxito el implante percutáneo de una prótesis valvular aórtica CoreValve y se describen los criterios para la selección de pacientes y la técnica de implante percutáneo.

Palabras clave > Válvula aórtica - Cateterismo - Endovascular - Prótesis valvular cardíaca

BIBLIOGRAPHY

1. Iung B, Baron G, Butchart EG, Delahaye F, Gohlke-Barwolf C, Levang OW, et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. Eur Heart J 2003;24:1231-43.

2. Varadarajan P, Kapoor N, Bansal RC, Pai RG. Clinical profile and natural history of 453 nonsurgically managed patients with severe aortic stenosis. Ann Thorac Surg 2006;82:2111-5.

3. Varadarajan P, Kapoor N, Bansal RC, Pai RG. Survival in elderly patients with severe aortic stenosis is dramatically improved by aortic valve replacement: Results from a cohort of 277 patients aged > or =80 years. Eur J Cardiothorac Surg 2006;30:722-7.

4. Otto CM, Mickel MC, Kennedy JW, Alderman EL, Bashore TM, Block PC, et al. Three-year outcome after balloon aortic valvuloplasty. Insights into prognosis of valvular aortic stenosis. Circulation 1994;89:642-50.

5. Grube E, Schuler G, Buellesfeld L, Gerckens U, Linke A, Wenaweser P, et al. Percutaneous aortic valve replacement for severe aortic stenosis in high-risk patients using the second- and current third-generation self-expanding CoreValve prosthesis: device success and 30-day clinical outcome. J Am Coll Cardiol 2007;50:69-76.

6. Piazza N, Grube E, Gerckens U, den Heijer P, Linke A, Luha O, Ramondo A, Ussia G, Wenaweser P, Windecker S, Laborde JC, de Jaegere P, Serruys PW. Procedural and 30-day outcomes following transcatheter aortic valve implantation using the third generation (18 Fr) corevalve revalving system: results from the multicentre, expanded evaluation registry 1-year following CE mark approval. EuroIntervention 2008;4:242-9.

7. Erdogan HB, Kayalar N, Ardal H, Omeroglu SN, Kirali K, Guler M, et al. Risk factors for requirement of permanent pacemaker implantation after aortic valve replacement. J Card Surg 2006;21:211-5.