

Percutaneous Aortic Valve Replacement in Patients with Severe Aortic Stenosis and High Surgical Risk

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SUMMARY

Objective

Aortic valve replacement is the treatment of choice in patients with aortic stenosis. However, a significant number of patients are not candidates for surgery due to high surgical risk and to the presence of comorbidities. Percutaneous aortic valve replacement represents an alternative option to conventional aortic valve surgery for selected high risk patients.

Material and Methods

To inform about the initial experience with percutaneous aortic valve replacement with a self-expanding CoreValve® aortic valve prosthesis (Medtronic, Minneapolis, MN, USA).

Results

Mean age was 80.8 ± 7.1 years (range: 63-90); 57% were men. Mean aortic valve area was 0.59 ± 0.25 cm² and mean EuroSCORE was $18.1\% \pm 4\%$. The percentages of patients in functional class III and IV were 73% and 27%, respectively. The procedure was successful in 95.2% (20/21) of patients, with a pronounced reduction in peak transvalvular aortic gradient (from 82 ± 14 mm Hg to 12 ± 3 mm Hg; $p < 0,001$); 14% of patients developed moderate to severe aortic regurgitation after the procedure. 85.5% of patients evolved to FC I. Definite pacemaker implantation was required in 38% (8/21). Procedure-related mortality was 4.7% and mortality after 30 days was 9.5%. One patient developed a minor stroke with complete recovery within a week. Four patients died in the long-term follow-up (median 7 months): 2 due to cardiac causes (cardiac mortality 19%) and 2 due to non-cardiac causes.

Conclusions

Percutaneous aortic valve replacement with CoreValve® aortic valve prosthesis is a feasible option for patients with high surgical risk that is associated with significant clinical improvement. The adequate selection of patients, improvement of the surgical technique and the development of new devices will increase the efficacy and safety of the procedure.

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Key words > Aortic valve stenosis – Percutaneous aortic valve replacement

Abbreviations > AVRS: Aortic valve replacement surgery | AS: Aortic stenosis

BACKGROUND

Aortic valve stenosis (AS) is the most frequent valvular heart disease in the Western world and has poor prognosis with medical treatment. (1) Aortic valve replacement surgery (AVRS) is the treatment of choice in these patients, producing relief of symptoms and increasing survival. (2, 3) However, a significant number of patients are not candidates for surgery due to high surgical risk. (4) Mortality increases

significantly in older patients. (3) Other comorbidities which increase surgical risk are left ventricular dysfunction, concomitant coronary artery disease, previous myocardial revascularization surgery and chronic obstructive pulmonary disease. Thus, one third of patients with AS are not candidates for AVRS due to the presence of significant comorbidities. (1, 5) Percutaneous aortic valve replacement is an innovative technique that is being incorporated

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to clinical practice with ongrowing enthusiasm, particularly in patients with high risk for surgery. (6)

The goal of the present study is to present the initial experience with percutaneous aortic valve replacement using a self-expanding CoreValve® (Medtronic, Minneapolis, MN, USA) aortic valve prosthesis.

MATERIAL AND METHODS

Study design and selection of patients

We conducted a prospective multicenter registry of consecutive patients undergoing percutaneous aortic valve replacement. Patients were selected by a multidisciplinary team (clinical cardiologists, interventional cardiologists, cardiovascular surgeons and specialists in diagnostic imaging). A total of 21 patients with severe symptomatic AS and high surgical risk were eligible for percutaneous aortic valve replacement in four high complexity cardiovascular centers. All patients were evaluated with transthoracic and/or transesophageal echocardiography (if the transthoracic study was not conclusive to determine the diameter of the aortic valve annulus), coronary angiography with aortography and angiography of the iliac and femoral tree. In some cases, patients underwent contrast-enhanced multi-detector row computed tomography (Figure 1). The operative risk was estimated by the logistic EuroSCORE.

The inclusion criteria were the following: patients with severe, symptomatic AS with echocardiographic criteria of severity (aortic valve area < 1 cm², < 0.6 cm²/m², peak velocity > 4.0 m/s or mean gradient > 40 mm Hg). The diameter of the aortic annulus measured by transthoracic and/or transesophageal echocardiography should be ≥ 20 mm and ≤ 27 mm, and a diameter of the ascending aorta at the level of the sinotubular junction ≤ 45 mm (Figure 1).

The following were considered exclusion criteria: bicuspid aortic valve, presence of thrombi in the left heart chambers, ejection fraction < 20%, iliac and femoral arteries with diameter < 6 mm or significant tortuosity of these arteries which could cause difficulty in advancing the catheters (Table 1). The procedure was considered successful

when the prosthesis was correctly implanted (evaluated by angiography and echocardiography) in the absence of mortality during the procedure.

Device description

The CoreValve® aortic valve prosthesis consists of a trileaflet bioprosthetic pericardial tissue valve that is mounted and sutured in a self-expanding nitinol stent. The valve is implanted using the retrograde approach. 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 origin of the coronary arteries, and the upper portion is flared to fixate the stent in the ascending aorta and to provide longitudinal stability and proper alignment. The current profile of the prosthesis is 18 F. The prosthesis is available in two sizes: 26 mm for aortic annulus diameter between 20 and 23 mm and 29 mm for aortic annulus diameter between 23 and 27 mm.

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 evaluate the presence, mechanism and severity of aortic regurgitation. A transient pacemaker is implanted (preferably via the jugular vein) 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 a 18F (6 mm) 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

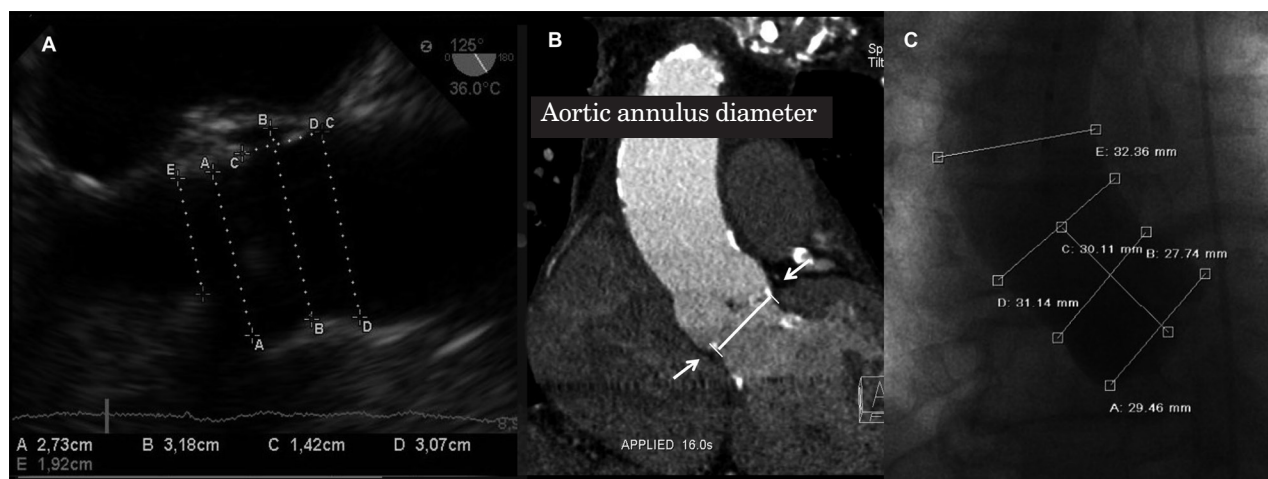


Fig. 1. **A** Transesophageal echocardiography, longitudinal view at 137°. See the different pre-procedural measurements. **A:** Aortic annulus. **B:** Sinuses of Valsalva. **C:** Distance from the sinus of Valsalva to the sinotubular junction. **D:** Sinotubular junction. **E:** Left ventricular outflow tract. **B.** Contrast-enhanced multi-detector row computed tomography image. **A:** Axial plane at the level of the valve showing maximal and minimal aortic valve diameters. **B.** Diameter of aortic annulus measured at the coronal plane. **C.** Distance between the annulus and both coronary ostia. **C.** Aortography of the ascending aorta with the necessary measurements to evaluate the feasibility of percutaneous aortic valve replacement.

Table 1. Simplified table describing the anatomical selection criteria to decide the implantation of a CoreValve®

Diagnostic findings	Echo	CT/MRI	Angiography	Recommended	Not Recommended
Ventricular thrombus x				Absent	Present
Subaortic stenosis	x	x	x	Absent	Present
LV ejection fraction	x		x	≥ 20%	< 20% without contractile reserve
Mitral regurgitation	x			≤ Grade 2	> Grade 2 due to organic disease
Vascular access diameter		x	x	≥ 6 mm	< 6 mm
Aortic and vascular disease		x	x	Absent to moderate	Severe
LV hypertrophy	x	x		Normal to moderate, 0.6-1.6 cm	Severe ≥ 1.7 cm
Coronary artery disease		x	x	Absent, mild or distal lesions > 70%	Proximal lesions >70%
Aortic arch angulation		x	x	Severe angulation	Acute angle
Aortic root angulation		x	x	< 30°	30 - 45°
Aortic and vascular disease		x	x	Absent or mild	Moderate to severe
Vascular access diameter		x	x	> 6 mm	Calcification and tortuosity < 7 mm

Indications for 26-mm CoreValve device	Echo	CT/MRI	Angiography	Recommended	Not Recommended
Annulus diameter	x	x		20-23 mm	< 20 mm or > 23 mm
Ascending aorta diameter		x	x	≤ 40 mm	≥ 40 mm
Sinuses of Valsalva diameter	x	x	x	≥ 27 mm	< 27 mm
Sinuses of Valsalva height	x	x	x	≥ 15 mm	< 15 mm

Indications for 29-mm CoreValve device	Echo	CT/MRI	Angiography	Recommended	Not Recommended
Annulus diameter	x	x		24 - 27 mm	< 24 mm or > 27 mm
Ascending aorta diameter		x	x	≤ 43 mm	≥ 43 mm
Sinuses of Valsalva diameter	x	x	x	≥ 29 mm	< 29 mm
Sinuses of Valsalva height	x	x	x	≥ 15 mm	< 15 mm

femoral access; in addition, access may also be gained via an extraperitoneal approach to the common iliac artery, placing sutures to secure the catheter. A pigtail catheter is introduced via the femoral or radial artery and positioned at the level of the non coronary sinus 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, aortic valvuloplasty is performed with a balloon with a diameter similar to that of the aortic annulus under ventricular pacing at 180 to 200 beats/min until systemic blood pressure decreases to < 40 mm Hg. Then, the device is advanced through the femoral artery and positioned at the level of the valve annulus. 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.

Antiplatelet and antithrombotic medication

All patients received 100 mg of aspirin before the procedure and daily thereafter. In addition, a loading dose of clopidogrel was administered to all patients, followed by 75 mg/day for

at least 3 months. Heparin sodium was administered during the procedure (80-100 U/kg).

Patient care after the procedure

After the procedure, all patients were admitted to the coronary care unit for continuous monitoring during 72 hours. The transient pacemaker was removed in the absence of rhythm disturbances. A definite pacemaker was implanted in case of atrioventricular block. Each center had different criteria for indicating pacemaker implant.

Follow-up

All patients were followed-up for 30 days and every 6 months thereafter. Mean follow-up was 7 months (25-75% interquartile range: 1-12 months).

Statistical Analysis

Continuous variables are expressed as mean ± standard deviation and categorical variables as numbers and percentages. Variables with non parametric distribution are expressed as medians and interquartile range. The paired samples t test was used to compare pressure gradients before and after the procedure.

We used the Kaplan-Meier method to perform a survival study. Statistical analysis was performed using SPSS 10 statistical package (Chicago, IL, USA).

RESULTS

Characteristics of the population

We included 21 consecutive patients [57% were men; mean age: 82 years (IQR 25% - 75%: 26-86)] from March 2009 to October 2010. The principal characteristics of the study population are described in Table 2. All patients presented severe, symptomatic AS with peak and mean transvalvular aortic gradient of 82 ± 14 mm Hg (range: 61-125) and 47 ± 6 mm Hg (range: 36-68), respectively. Mean aortic valve area, estimated by echocardiography before the procedure, was 0.59 ± 0.25 cm² and valvular annulus measured 23.6 ± 2.2 mm (range 20-26). Mean logistic EuroSCORE was $18.1\% \pm 4\%$, and in 28% logistic EuroSCORE was $\geq 20\%$. The percentages of patients in functional class III and IV were 73% and 27%, respectively.

Procedure

The femoral artery was accessed in all patients. The procedure ended successfully in 20 of 21 cases. A 26-mm prosthesis was implanted in 41% of patients (for aortic annulus diameter between 20 and 23 mm), and the remaining patients received a 29-mm prosthesis (for aortic annulus diameter between 23 and 27 mm). The availability of valve prosthesis with different sizes will allow the indication of this procedure to patients with smaller or greater annulus in a near future. Eight patients (38%) required subsequent valvuloplasty with balloons measuring from 23 to 30 mm. After valve implantation, peak instantaneous transaortic pressure gradient measured by echocardiography was 12 ± 3 mm Hg (Figure 2). One patient presented severe residual aortic regurgitation (patient 10) unresponsive to valvuloplasty and two patients developed moderate valvular regurgitation

defined by echocardiography. None of the patients presented clinical signs of heart failure. Percutaneous closure devices were successfully used in all 5 cases that used this procedure. Surgical dissection of the femoral artery was used in the remaining cases.

Complications of the procedure

During valvuloplasty (before dilation) two patients presented rupture of the aortic annulus; one of these patients died in the catheterization laboratory due to massive bleeding and the other patient was stabilized after undergoing valve implant and pericardiocentesis. In both cases, the diameter of the pre-dilation balloon and of the valve annulus were the same. Nowadays, the diameter of the pre-dilation balloon used is smaller than that of the valve annulus. The procedure was successful in patient 3; yet the patient presented poor in-hospital outcomes and died 30 days after due to multiorgan failure associated with pulmonary thromboembolism. Another patient underwent the implant of a second prosthesis as the first one was implanted in a high position (patient 10). The second procedure was successful; however, the patient developed a minor stroke with complete recovery within a week. Eight patients (38%) required implantation of a definite pacemaker due to AV block. There were no conversions to open AVRS. Procedure-related mortality was 4.7% (1/21) and 9.5% (2/21) at 30 days. Mean in-hospital stay was 10.3 days. The procedures were performed by a multidisciplinary team of interventional cardiologists, specialists in diagnostic imaging, anesthesiologists and cardiovascular surgeons. During this initial stage, all the procedures were performed with the cooperation of a highly experienced physician trained in percutaneous aortic valve replacement. We did not find any association between the rate of complications

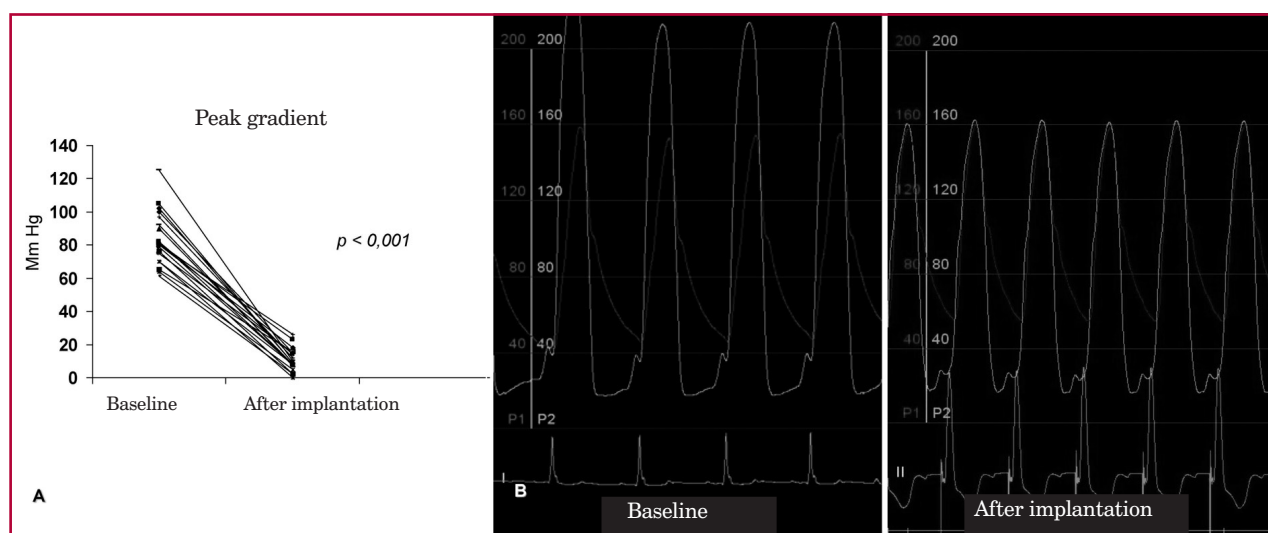


Fig. 2. Left: Baseline gradient and gradient after percutaneous implantation. Right: Measurement of intraventricular and aortic pressures in a patient, showing absence of transvalvular aortic gradient after the implantation.

Table 1. Simplified table describing the anatomical selection criteria to decide the implantation of a CoreValve®

Patient	Age	Gender	BMI	FC	AVA	Peak gradient	Mean gradient	AR severity	EuroSCORE	Comorbidities
1	90	F	26	III	0,8	80	52	Mild	14,4	
2	89	F	21	III	0,23	81	43	Moderate	25,3	Breast cancer, Lymphoma
3	82	F	27	IV	0,8	82	40	Mild	13	CAD
4	63	M	26	III	0,5	65	47	Mild	10	CABGS
5	79	F	26	III	0,59	70	40	Mild	22,15	Previous PCI, COPD
6	90	M	31	III	0,69	102	57	No	9,6	Previous PCI, AF
7	88	M	28	III	0,63	97	66	Moderate	13	CAD
8	72	M	30	III	0,6	70	41	Mild	19,8	COPD, CKF, liver TX
9	82	F	25	III	0,7	63	41	Mild	14,8	COPD
10	80	M	29	IV	0,6	100	58	Mild	13,6	One kidney
11	74	M	25	III	0,5	105	59	No	18	Stroke, CAD, AMI
12	69	M	26	III	0,7	90	50	No	20	Previous aortic valvuloplasty
13	80	F	29	III	0,6	76	41	Mild	22,1	Lung cancer
14	85	F	25	III	0,63	64	38	Moderate	46,8	Previous aortic valve replacement
15	83	M	24	IV	0,46	79	47	Mild	6,6	Chronic myeloid leukemia
16	76	M	39	III	0,6	80	50	No	15	COPD
17	84	M	24	IV	0,75	61	38	Mild	19	Kidney tumor
18	76	M	30	III	0,7	125	78	No	11,4	CABGS, Aortic valve replacement
19	83	F	24	IV	0,4	85	45	No	22,3	AF, CAD
20	86	M	25	IV	0,52	71	40	Mild	19,7	AF, CAD
21	86	F	25	III	0,75	100	77	Mild	11,3	--
Mean	80,8 ±		26,3 ±		0,59 ±	82 ±	47 ±		18,1 ±	
	7,1		5,3		0,25	14	6		4	

and the volume of patients treated in each center.

Follow-up

Four patients died after the first month of follow-up: 2 due to cardiac causes and 2 due to non-cardiac causes. Patient 8 presented significant improvement of symptoms after valve implantation; however, 30 days after, the patient's functional class deteriorated due to subacute endocarditis of the mitral valve. This patient had a previous moderate mitral regurgitation that was not modified during the procedure and died due to heart failure 60 days after the intervention. Overall survival estimated by the Kaplan-Meier method was 77.8% (Figure 3), while 85.8% of those patients who survived evolved to functional class I.

DISCUSSION

Severe aortic stenosis is the most common acquired valvular heart disease and its prevalence significantly increases with age, reaching 5% in > 75 years. (7) During the last years, several therapeutic options have been described for the treatment of severe AS (AVR surgery with mechanical heart valve prostheses, stented and stentless bioprostheses, aortic homografts and Ross procedure). (9-11) Aortic valve replacement surgery represents the standard treatment, producing

relief of symptoms and increasing survival. However, the surgical approach is difficult in patients with high surgical risk, especially in old subjects or in those with comorbidities. Aortic valvuloplasty represents a valid therapeutic option in hemodynamically unstable patients or in those with high surgical risk. Yet, the value of this intervention is merely palliative as it is commonly associated with recurrence of symptoms. (12) The recent development of percutaneous aortic valve replacement offers a long-lasting treatment in patients unsuitable for AVRS. (13, 14) Although initially the procedure was very complex, it has become simpler as a consequence of the rapid technological advances and to the learning curve. An adequate selection of cases is essential for the success of the procedure. The possibility of using a femoral access is evaluated (femoral and iliac arteries diameter > 6 mm without excessive tortuosity). The anatomical criteria must be met according to the percutaneous aortic valves currently available (aortic annulus diameter 20/27 mm, ascending aorta < 45 mm and sinus of Valsalva height > 10 mm, the angle between the aorta and the left ventricular outflow tract and calcifications of the valvular apparatus). The hemodynamic results are excellent with the devices currently used, producing an outstanding improvement of the functional capacity.

(15) In our experience, percutaneous implantation of a CoreValve® aortic valve prosthesis in patients with severe AS was successful in most cases, with significant functional improvement and a reasonable survival at 30 days of follow-up. Our results reproduce the information previously reported demonstrating that the technique is feasible and efficient, with acceptable mortality rate considering the high surgical risk.

The need of implanting a definite pacemaker after the procedure is common (38% in our series) and consistent with the rate reported by Grube et al. (33.3%). (13) These rates are higher than those published in series using percutaneous implant of the Edwards-Sapien® (Edwards Lifesciences Inc, Irving, CA, USA) prosthesis and in other surgical series: 6 - 6.5%. (16-18) The CoreValve® may be implanted in a low position with subsequent development of conduction disturbances, especially in patients with previous bundle branch block. Low positioning of the Edwards-Sapien® valve is uncommon. However, the high rate of implantation of definite pacemaker may also be the result of a prophylactic indication due to lack of knowledge of the clinical outcomes.

The development of vascular lesions represents a limitation to the retrograde approach. In consequence, it is essential to determine the diameter of the iliac and femoral vessels, presence of calcifications, tortuosity or previous lesions to prevent this complication. Subclavian access or transapical implantation should be considered when the femoral approach is not feasible. (19, 20) Fortunately, the retrograde approach via the femoral artery was possible in all cases and there were no vascular complications. This might be partially due to the fact that valve implantation was made through an 18 F introducer (21), while the Edwards-Sapien® valve currently requires 22 F and 24 F for valve diameters of 23 mm and 26 mm, respectively.

The development of periprosthetic leak following the implantation was common, with an incidence

similar to that of recent reports; only one patient presented severe regurgitation. Despite the high incidence of periprosthetic leak, studies based on echocardiographic findings have demonstrated that this type of leak and valve integrity remain stable, left ventricular mass decreases and left ventricular function improves in the mid-term.

Two patients presented rupture of the aortic valve annulus during pre-dilation; both patients evolved with unfavorable outcomes. We consider important to avoid large balloons for valve pre-dilation and to use balloons smaller than the diameter of the annulus in patients with excessive calcifications. A considerable learning curve has to be overcome before cardiologists, surgeons and specialists in diagnostic imaging working together during percutaneous aortic valve replacement have the optimal knowledge and skills to perform the procedure. This includes the different techniques (transfemoral, transapical and transsubclavian approaches, among others) and devices (CoreValve or Edwards-Sapiens®). Probably, the development of complications during the procedure (rupture of the aortic annulus, incorrect positioning of the valve prosthesis, cardiac tamponade, severe periprosthetic leak and definite pacemaker implantation, among others) will decrease with the learning curve of the procedure and with the development of new devices.

Study Limitations

This prospective and multicenter registry analyzed the outcomes of a small cohort of patients undergoing percutaneous aortic valve replacement with a prosthetic aortic CoreValve® during a short follow-up period (median follow-up: 7 months) and without comparing it with a control group (AVRS or percutaneous implant of other type of devices). Further studies including more patients and with longer follow-up are necessary to define the efficacy of the prosthesis.

CONCLUSIONS

Percutaneous implantation of a CoreValve® aortic valve prosthesis in patients with high surgical risk is a feasible and effective therapeutic option for selected patients.

The adequate selection of patients, improvement of the surgical technique and the development of new devices will increase the efficacy and safety of the procedure.

RESUMEN

Reemplazo percutáneo de la válvula aórtica en pacientes con estenosis aórtica grave y riesgo quirúrgico elevado

Introducción

La cirugía de reemplazo valvular aórtico es el tratamiento de elección en pacientes con estenosis aórtica. Sin embargo, en una proporción considerable de pacientes, el riesgo quirúrgico y la presencia de algunas comorbilidades, que aumentan este riesgo,

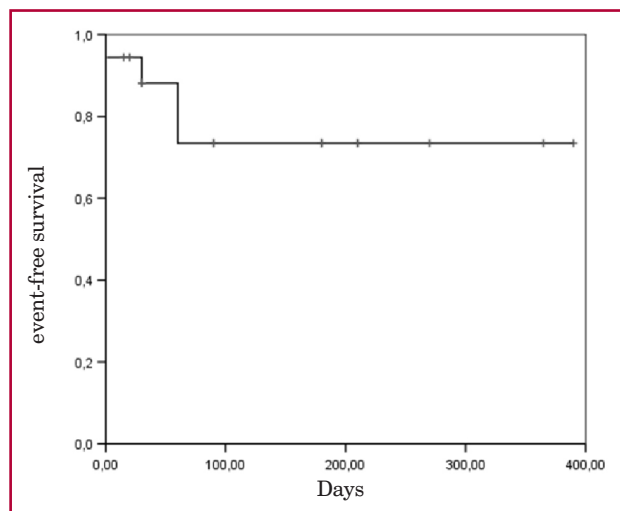


Fig. 3. Kaplan-Meier survival curve.

impiden la cirugía. El reemplazo percutáneo de la válvula aórtica representa una alternativa a la cirugía valvular convencional para pacientes seleccionados de riesgo elevado.

Objetivo

Comunicar la experiencia inicial de reemplazo percutáneo de la válvula aórtica con prótesis autoexpandible CoreValve® (Medtronic, Minneapolis, MN, USA) en pacientes portadores de estenosis aórtica grave.

Material y métodos

Registro multicéntrico en el que se incluyeron 21 pacientes con estenosis aórtica grave (área ≤ 1 cm²) sintomática y riesgo quirúrgico elevado sometidos a implante percutáneo en cuatro centros cardiovasculares argentinos de alta complejidad. Para el procedimiento se implementó una estrategia multidisciplinaria que involucró a diversos especialistas: anestesiólogo, cirujano, expertos en imágenes y cardiólogos intervencionistas.

Resultados

La edad media fue de $80,8 \pm 7,1$ años (rango: 63-90), el 57% de sexo masculino, área valvular media de $0,59 \pm 0,25$ cm² y EuroSCORE de $18,1\% \pm 4\%$. El 73% y el 27% de los pacientes se encontraban en clase funcional III y IV, respectivamente. El éxito del procedimiento fue del 95,2% (20/21), que se tradujo en una reducción pronunciada del gradiente pico transvalvular aórtico (82 ± 14 mm Hg a 12 ± 3 mm Hg; $p < 0,001$), mientras que el desarrollo posprocedimiento de regurgitación aórtica de grado moderado-grave fue del 14%. El 85,8% de los pacientes evolucionaron a clase funcional I. El requerimiento de marcapasos definitivo fue del 38% (8/21). La mortalidad del procedimiento y a los 30 días fue del 4,7% y del 9,5%, respectivamente; se observó un caso de accidente cerebrovascular isquémico menor con restitución ad integrum dentro de la semana. Se detectaron 4 óbitos en el seguimiento alejado (mediana 7 meses), dos de origen cardíaco (mortalidad cardíaca 19%) y otros dos de causa no cardíaca.

Conclusiones

El tratamiento de la estenosis aórtica grave en pacientes de riesgo quirúrgico elevado mediante reemplazo valvular percutáneo con prótesis CoreValve® es una alternativa factible que se asocia con una mejoría funcional notoria. La selección adecuada de pacientes, el perfeccionamiento de la técnica del procedimiento y el desarrollo de nuevos diseños incrementarán su eficacia y seguridad.

Palabras clave > Estenosis de la válvula aórtica - Reemplazo percutáneo de válvula aórtica

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