Experience with aortic valve implantation with the self-expanding Portico valve: in-hospital results of a consecutive series of patients after 30 days, and at the long-term follow-up

Experiencia con el implante valvular aórtico con la válvula autoexpandible Portico: resultados hospitalarios, a 30 días y en el seguimiento alejado de una serie consecutiva de pacientes

Carlos Fernández-Pereira[1,3,4], Juan Mieres[1,2], Hernán Pavlovsky[1,3], A. Matías Rodríguez-Granillo[1,3,4], Diego Azcarrunz-Catoretti[1,2], Carolina Salvatori [7], Norberto G. Allende[6], Valeria Curotto[5], Ricardo Pérez de la Hoz[5], Alfredo E. Rodríguez[1,2,3,4]

ABSTRACT

Approximately 10% of patients older than 75 years have some degree of aortic valve disease and 3.4% of them severe stenotic valve disease (AS). We present our experience with the Portico valve in 3 hospital in patients with AS. Overall, 40 patients were included in whom a Portico aortic prosthetic valve was implanted, which corresponds to 31.2% of our total TAVI experience. In this consecutive series of high risk patients or with a contraindication for SAVR, treatment with TAVI with the Portico device had a low rate of in-hospital complications and after 30 days. The 30-day mortality rate was 7.5% and the rate of permanent pacemaker implantation, 12.5%, which is lower than the one reported for this valve.Survival rate at the 15-month follow-up was 82.5% and the rate of survival free from cardiac death, 96.8% In this series of patients, to our knowledge the largest in our country with this type of valve, the implantation of the Portico valve was associated with similar results to those reported in the medical literature with other types of devices in this group of patients.

Keywords: *TAVI, TAVR, SAVR, aortic valve stenosis, elderly patient, valvular surgery.*

RESUMEN

Aproximadamente el 10% o más de los pacientes mayores de 75 años tienen algún grado de enfermedad de la válvula aórtica y el 3,4% de ellos presenta enfermedad estenótica severa de esta válvula (EAo). Presentamos nuestra experiencia con la válvula Portico en 3 centros hospitalarios en pacientes con EAo. En total se incluyeron 40 pacientes a los que se les implantó una válvula protésica aórtica Portico que corresponde al 31,2% del total de nuestra experiencia en TAVI. En esta serie consecutiva de pacientes de alto riesgo o contraindicación para SAVR, el tratamiento con TAVI con el dispositivo Portico mostró baja incidencia de complicaciones hospitalarias y a 30 días. La mortalidad a 30 días fue de 7,5% y la incidencia de marcapasos definitivo fue del 15%, que es menor al reportado para esta válvula. La sobrevida libre de muerte a 15 meses fue de 82,5% y la sobrevida libre de muerte cardíaca, de 96,8%. En esta serie de pacientes, a nuestro conocimiento la más extensa de nuestro país con esta válvula, el implante de válvula Portico estuvo asociado a resultados similares a lo reportado en la literatura con otros tipos de dispositivos en este grupo de pacientes.

Palabras clave: *implante percutáneo de válvula aórtica, cirugía valvular aórtica, estenosis valvular aórtica, pacientes añosos, cirugía valvular.*

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INTRODUCTION

Approximately 10% of the patients > 75 years have some degree of aortic valve disease and 3.4% of them even severe aortic stenosis (AS), which may have public health implications in this age group.

Back in 2002, Dr. Alain Cribier was the first cardiologist to perform a transcatheter aortic valve implantation (TAVI) procedure in France in an inoperable patient. Since then, the indications for this procedure have been growing nonstop, as well as the experience of the operators in the use of this technique, and the design and improvement of the valves.

The growth in the indications for TAVI reported over the last few years has been estimated at around 40% per year in the Western world. As a matter of fact, to this date, it exceeds the number of conventional surgical aortic valve replacement (SAVR) procedures performed.

At the beginning, this procedure was performed with a balloon-expandable valve (Edwards-Sapiens), but a self-expanding design rapidly took over (Evolut-Medtronic) (1-7).

Then, new valve designs entered the market, most self-expanding heart valves, that proved effective for the percutaneous management of AS (8-11).

However, only two self-expanding valves showed results that were similar to the ones reported with the balloon-expandable valve (Edward-Sapiens) in randomized studies. These were the Evolut (EV) self-expanding valves, and the Portico self-expanding valve (Abbott-Saint Jude), both manufactures with a large experience in the design of conventional heart valves.

Our group started performing this procedure back in 2009 and, until the present time, 128 TAVIs have been performed all by the same interventional cardiologists. The aim of this study is to report our own experience on all the TAVIs performed consecutively with the Portico device. As far as we know, this is the largest experience ever reported in our country and in our region with this device.

1. Servicio de Cardiología Intervencionista, Sanatorio Otamendi, CABA
2. Servicio de Cardiología Intervencionista, Sanatorio Las Lomas, San Isidro, Buenos Aires
3. Servicio de Cardiología Intervencionista, Clínica IMA, Adrogué, Buenos Aires
4. Centro de Estudios en Cardiología Intervencionista, CABA
5. Servicio de Cardiología, Sanatorio Otamendi, CABA
6. Servicio de Cardiología, Clínica IMA, Adrogué, Buenos Aires
7. Secretaria Científica Consejo de Cardiología Clínica y Terapéutica SAC, CABA

✉ Corresponding author: *Carlos Fernández Pereira. Larrea 910 4 Piso A, C1125AAC CABA, Argentina. Tel.: 01149629012. Fax: 01149648721. cfernandezpereira@centroceci.com.ar*

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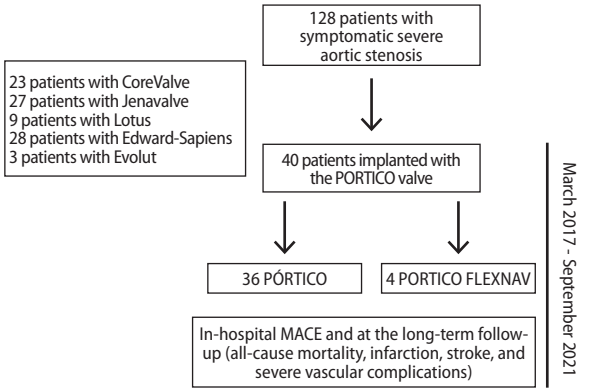

Figure 1. *Study population, overall number of patients treated with TAVI and with the Portico valve, and reason for this presentation.*

MATERIAL AND METHODS

Study design

This is a retrospective and longitudinal follow-up registry that studied all patients treated with TAVI from March 2009 through August 2021 in 3 cath labs from the *Centro de Estudios de Cardiología Intervencionista*, Buenos Aires, Argentina, who were consecutively included in the registry.

Data were extracted from the TAVI prospective registry of the *Centro de Estudios de Cardiología Intervencionista*, Buenos Aires, Argentina from a web-based database with a standardized form including case reports with consecutive information on the demographic, clinical, angiographic, and echocardiographic characteristics of all patients treated with transcatheter aortic valve implantation. All the patients who did not receive the Portico valve were excluded from this registry of 128 patients. The study population that was left was, therefore, reduced to 40 patients **(Figure 1)**, that is, all patients consecutively treated with TAVI with the Portico valve (Abbott-Saint Jude) between February 2017 through August 2021 at the cath labs of Centro CECI in Buenos Aires, Argentina.

The Portico valve consists of a bovine pericardial prosthesis mounted on a self-expanding nitinol stent. This prosthesis is fully repositionable, and the valve starts to work immediately during implantation. The location of the stent cells also facilitates accessing the coronary arteries. A complete description of this valve has already been published. (12)

Endpoints

This study primary endpoint was to know the in-hospital mortality rate and the rate of major adverse cardiovascular events (MACE) at 30 days and at the long-term follow-up (death, major stroke, and severe vascular complications). Severe vascular complications were defined as those that required the transfusion of two red blood cell units and/or surgical repair.

The study secondary endpoints were to analyze the previous valve gradient and area immediately after the implant and at the long-term follow-up.

The rate of changes on the electrocardiogram (EKG) after implantation and the need for permanent pacemaker implantation after TAVI and its comparison with the non-Portico implants of our series are also a matter of secondary analysis. Deaths occurred both during index hospitalization and valve implantation were considered cardiovascular.

TABLE 1. Baseline clinical and angiographic characteristics.

Variable	N
No. of patients	40
Age, years	80.9±7.8
Sex, male, %	63.1
Arterial hypertension, %	72.5
Dyslipidemia, %	47.5
Smoking habit, %	12.5
Diabetes, %	12.5
Chronic kidney disease, %	15.0
Dialysis, %	2.5
Previous revascularization, %	27.5
Previous CABG, %	20.0
Angioplasty, %	27.1
Previous surgical aortic valve replacement, %	10.0
Peripheral vascular disease, %	15.0
Moderate or severe COPD, %	35.0
Previous stroke/TIA, %	12.5
Overweight, %	32.5
Anemia, %	15.0
Previous pacemaker, %	15.0
First-degree AV block, %	23.5
RBBB, %	2.9
First-degree AV block + RBBB, %	23.5
EuroSCORE, %	11.8±2.8

TIA: transient ischemic attack. RBBB: right bundle branch block.

Both the results of the gradient and the readings of valvular flow velocity obtained at the transthoracic echocardiographic 6-month follow-up were studied too.

Implantation procedure

The Portico valve implantation procedure was performed by the same interventional cardiologists (AER, CFP, and JM) in all the cases.

All cases were non-aggressively predilated with a balloon of a size that was always inferior to the minimum diameter of the aortic annulus on the multislice computed tomography coronary angiography and under a high-frequency transient pacemaker.

After implantation, postdilatation was only used in the presence of moderate residual valvular regurgitation and based on the readings provided by the transthoracic echocardiogram.

The transthoracic echocardiography was used in all cases after implantation to assess the degree of stenosis and/or residual valvular regurgitation. Also, to rule out the possibility of pericardial effusion.

The size of vascular access, valve annulus, height of coronary ostia, and pre-implantation planning was guided through a multislice computed tomography coronary angiography.

Patients received a 6-month course of dual antiplatelet therapy (DAPT) except for those already anticoagulated who received this course plus a 1-month only course of anticoagulation followed by P2Y12 inhibitors plus anticoagulation.

A cine coronary arteriography was selectively performed before implantation in all the cases. Only lesions considered severe in the main vessels by visual estimation using the ERACI anatomical risk score criteria were treated. (13)

Statistical analysis. Regarding the statistical analysis, the discrete variables were expressed as frequencies (percentage of patients), and the continuous ones as mean and standard deviation. *P* values were estimated using the Student *t* test, the chi-square test or Fisher's exact test, when appropriate. The statistical software package SPSS v.17.7 (IBM Corp, Armonk, NY, United States) was used to perform the analysis.

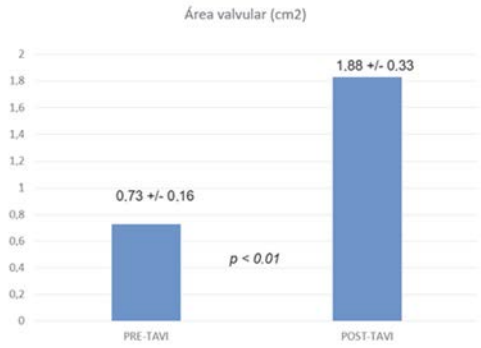

Figure 2. *Valvular area (cm²) before and immediately after the implant.*

TABLE 2. Procedural characteristics.

Variable	N
Nº Patients	40
Age, years	80.9±7.8
Femoral access, %	97.5
Valve-in-valve, %	3
Valve no. 23, %	20.0
Valve no. 25, %	25.0
Valve no. 27, %	22.5
Valve no. 29, %	32.5
Postdilatation, %	5.02
Volume of contrast used, ml	226±65
Preoperative creatinine levels, mg/dl	1.1±0.3
Postoperative creatinine levels (48 hours), mg/dl	1.2±0.8
Fluoroscopy time, min	29.3±12.6
Hospital stay, days	5.8±6.1
Successful implantation procedure, %	100

RESULTS

A total of 40 patients implanted with a Portico aortic valve prosthesis were included. This represented 31.2% of the entire TAVI experience of our center (14). The first patient was treated back in March 2017, and all the patients treated until September 2021 have been included in this series.

All patients underwent a 30-day follow-up when this report came out. The median follow-up was 15.8 months +-9.5. The mean age was 80.9 +/- 8.1 years, and 64.5% of the patients were men. Euroscore II was 11.8 +/- 2.8.

Except for two patients, the rest were patients of high surgical risk and/or with a direct contraindication to conventional surgery.

Femoral access was used in 97.5% of the cases while in the remaining ones, the axillary artery was used. All patients were treated via surgical arterial dissection in the artery where the valvular device would eventually be implanted. No puncture or percutaneous wound closure were used in this series.

The first model of valve was used in 36 patients while in the remaining 4 the FlexNav design was used.

A total of 4 patients had already undergone a previous SAVR (10%), and 47.1% a previous myocardial revascularization surgery and/or a previous coronary angioplasty. The baseline demographic characteristics of the 40 patients are shown on **Table 1**.

Valve implantation was technically successful in 100% of the cases. No transient pacemaker was used regarding valve implantation. Similarly, no cerebral protection device was used either.

Two patients with significant ventricular hypertrophy showed cardiac tamponade probably due to the hydrophilic guidewire used to access the left ventricle (3). Both patients were drained at the cath lab with good disease progression, and eventually discharged 4 to 5 days after the implant.

A total of 33 patients (82.5%) did not show aortic regurgitation in the thoracic aortogram performed after the implant. Mild paravalvular leak, however, was reported in 5 patients (12.5%) while in the remaining 2 it was moderate to severe. Both patients required dilatation with an oversized balloon to correct the leak.

The procedural characteristics are shown on **Table 2**.

Immediately after the implant, two patients showed signs of minor strokes with clinical resolution and without focal signs within the first 30 days. No in-hospital major strokes were reported in the entire series or at the 30-day follow-up.

A total of 3 patients died at the 30-day follow-up. All deaths were considered cardiovascular (7.5%). One death was due to severe metabolic acidosis probably due to acute lower limb ischemia for prolonged clamping of the peripheral arterial distal bed 7 days after the implant. The second patient suffered acute generalized widespread bleeding within the first 24 hours. The third one had an intermittent AV block after the implant while waiting for permanent pacemaker implantation. Afterwards, a previously treated digestive bleeding relapsed followed by bilateral pneumonia, and severe hypoxia (maybe COVID 19?). The patient died 10 days after TAVI due to cardiac arrest.

A total of 11 patients (27.5%) developed a new right bundle branch block (RBBB) during hospitalization, and 5 additional patients required permanent pacemaker implantation. All these patients had previous conduction disorders.

Both disease progression and complications of the 40 patients at the 30-day follow-up are shown on **Table 3**.

The transthoracic echocardiogram performed after the implant confirmed that the valvular area improved significantly from 0.73 to 1.88; $P < .01$ **(Figure 2)**.

Long-term follow-up

All the patients discharged from the hospital underwent clinical follow-up (37/37 100%).

A total of 4 patients (10.8%) died at the follow-up. Three of these were described as noncardiac deaths (pneumonia, lung cancer, and COVID 19) while the last one occurred in a female patient treated with valve implantation at the 3-year follow-up with a normofunctioning valve according to the echocardiogram, who underwent sudden and progressive dyspnea in < 24 hours. The patient eventually died of a ventricular arrhythmia (suspected pulmonary thromboembolism). The cardiac death-free survival rate of patients at the 6-month follow-up was 96.8% (31/32). The overall 30-day mortality rate and at the long-term follow-up was 17.5% (7/40).

The death-free survival rate and the rate of MACE are both shown on **Table 3**.

A total of 2 patients underwent successful angioplasty revascularization at the follow-up (5%).

In the follow-up echocardiography performed, the gradient measured on the transthoracic echocardiography significantly reduced the mean gradient after valve implantation, $P < .001$; peak $P < .001$; and flow velocity, $P < .001$ **(Figure 3)**.

The rate of permanent pacemaker implantation with the self-expanding Portico valve after 1 year was 15% (6/40), which is somehow similar to the overall rate reported in our series [18.4% (14)], and numerically lower compared to other non-Portico valve implantations of the series [6/40 vs 18/88 (15% vs 20.4%, respectively $P = .37$)].

TABLE 3. Clinical events.

In-hospital events (procedural and at the 30-day follow-up)	n=40
	% (n)
All-cause mortality, %	7.5 (3/40)
Cardiac death, %	7.5 (3/40)
Minor stroke, %	5.0 (2/40)
Severe vascular complications, %	15.0 (6/40)
Cardiac tamponade, %	5.0 (2/40)
MACE, %	25 (10/40)
New left bundle branch block, %	27.5 (11/40)
Need for transient pacemaker, %	20.5 (8/40)
Need for a permanent pacemaker, %	12.5 (5/40)
Events at the follow-up (15,2±6 months)	**n=37**
All-cause mortality, %	10.8 (4/37)
Cardiac death, %	2.7 (1/37)
Myocardial infarction, %	0.0 (0/37)
Revascularization, %	5.4 (2/37)
Major stroke, %	2.7 (1/37)
Permanent pacemaker %	2.7 (1/37)
Overall MACE, %	13.5 (5/37)
Eventos acumulados (intrahospitalarios y durante el seguimiento) n=40	
Overall all-cause mortality, %	17.5 (7/40)
Overall cardiac death, %	10.0 (4/40)
Overall myocardial infarction, %	0.0 (0/40)
Overall revascularization, %	5.0 (2/40)
Permanent pacemaker, %	15.0 (6/40)
Major and minor stroke, %	7.5 (3/40)
Overall MACE, %	30 (12/40)

MACE: death, infarction, major stroke, and severe vascular complications.

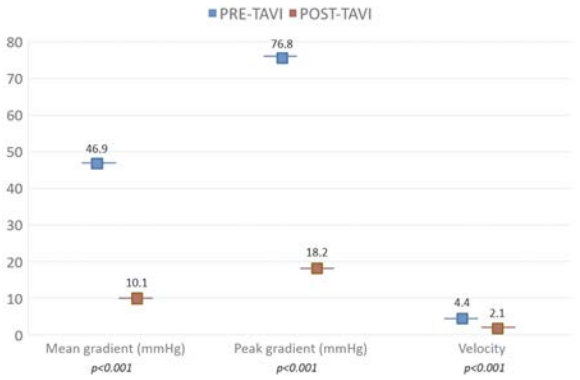

Figure 3. *Peak and mean gradients and valvular flow velocity as seen on the echocardiography before the implant and at the 6-month follow-up.*

DISCUSSION

In this consecutive series of high-risk patients or with a contraindication to SAVR, the transcatheter aortic valve implantation (TAVI) procedure with the Portico self-expanding valve showed a low rate of in-hospital complications and at the 30-day follow-up. The 30-day mortality rate was 7.5%.

Survival rate at the median follow-up was 82.5% while the patients' cardiac death-free survival at the > 6-month follow-up was nearly 97%, indicative of how effective the treatment really was.

Similarly, both the valvular area and gradient improved significantly after TAVI at the long-term follow-up (figures 2 and 3).

The results of this study should be put into context based on the target patients' clinical profile.

As described in the results, except for two patients, the rest of the patients followed the modality effective in our country on the indication for TAVI according to the Argentine Social Security system based on which only high-risk patients for SAVR can be accepted for TAVI (15).

What this means is that this population is far from the current European and/or American recommendations on indications for transcatheter aortic valve implantation given the recent positive results seen in low or intermediate risk patients in comparative randomized trials between TAVI and SAVR recently published like the PARTNERS 3, NOTION, SURTAVI, and the EVOLUT low risk trials. In these trials TAVI proved non-inferior to TAVI and reduced the rates of overall mortality and cardiovascular death in patients with low or intermediate risk (1.16-22).

Our patients were far from being a low or intermediate risk group, and our results should be compared with the first randomized clinical trials conducted in inoperable or high clinical risk patients (4-6).

For example, in the PARTNERS trial of high-risk patients the 1-year mortality rate of the TAVI group was 24.2%, which is somehow similar to the 17.5% rate reported in this series (5).

Similarly, we should mention that although no cerebral protection device was used the rate of major strokes reported at the follow-up was only 2.5%, which is lower compared to the high rate of stroke (5.1%) reported by the PARTNERS at the 1-year follow-up (5).

Also, these results should be put into context and compared to those obtained with SAVR in our country that in the last national registries (23) reported a 30-day mortality rate of nearly 9% with simple valvular replacement and 13.4% with combined surgery.

Finally, the rate of permanent pacemaker implantation was 15%, which is somehow lower compared to the one reported for this valve (11) and, in our own experience, numerically lower compared to the overall rate reported with non-Portico valves. Nonetheless, the use of this device was consistent with a greater knowledge of the technique by the group that performed the TAVI procedure (14). Although the rate of complete left bundle branch block after Portico valve implantation is 28% during the implantation process (24), 60% of these LBBBs resolve within 30 days. Consistent with these data, 27.5% of our population had a new LBBB after implantation.

Although long-term mortality does not seem to be associated with permanent pacemaker implantation post-TAVI (24), we honestly believe that it is the greatest challenge that we need solve for a routine use of this technique in young patients with low or intermediate risk.

Study limitations

This was a relatively small study sample with a new valve device on which only one non-inferiority study has been conducted with the 2 valves currently available in the United States. Although this study met the non-inferiority criteria at 1 year, it also confirmed the presence of more in-hospital events (25) probably due to the lack of experience of the heart team operating this device. Finally, although a post-hoc comparison confirmed a higher 2-year mortality rate with the Portico valve compared to the Edward Sapiens balloon-expandable valve, it was somehow similar to that of the Evolut Medtronic self-expanding vale. Also, the hemodynamics of the Portico valve was better than that of the Edward Sapiens balloon-expandable valve.

The valvular area was measured through Doppler echocardiography in most patients before and after valve implan-

tation. However, both the gradient and the velocity of flow were measured at the follow-up, which confirmed the good functioning of the valve as figure 3 shows.

CONCLUSIONS

As far as we know this is the largest series of consecutive patients of high clinical risk treated with the Portico valve ever published in our country. The implantation of the Portico valve was associated with low rates of in-hospital mortality and adverse events, and death-and-cardiac-death-free survival rates at the 1-year follow-up similar to those reported by the medical literature with other types of valves in this group of patients.

WHAT DOES THIS STUDY ADD?

Transcatheter aortic valve implantation (TAVI) has become the procedure of choice to treat high-risk aortic valve disease. Actually, the latest randomized clinical trials (RCT) conducted that compared it to surgical aortic valve replacement (SAVR) showed similar or even better survival rates at the 2-year follow-up with TAVI in low or intermediate risk patients.
Following these RCTs, both the American and the European guidelines recommend its use in these cases.
The comparative experience with SAVR was performed with the two valves more widely used today and approved for clinical use in the United States (Edwards Sapiens, and Evolut Medtronic). In our country, the experience and long-term results of other valves have not been reported extensively.
This study described a consecutive series of patients with TAVI implanted with the Portico self-expanding valve (Abbott-Saint Jude) in a group of high clinical risk patients.
The patients' > 1-year survival rate was 82.5% while the cardiac death-free survival rate at the > 6-month follow-up was 96.8%.
As far as we know, this is the largest series ever reported on the use of this valve in our country.

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