# Early experience of transcatheter aortic valve implantation at Sanatorio Dr. Julio Méndez - Mediter Diagnosis

## Experiencia inicial del implante percutáneo de la válvula aórtica en el Sanatorio Dr. Julio Méndez - Diagnóstico Mediter

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## ABSTRACT

Aortic stenosis is the most common valvular heart disease in our region and in the Western countries. As a matter of fact, it is considered the third leadingcardiovascular diseaseonly behind arterial hypertension and coronary artery disease.
A retrospective observational study of our first cases on transcatheter aortic valve implantation (TAVI) was conducted from September 2018 through March 2021. A total of 10 patients were included, 80% of whom were women (8 patients) with a mean age of 84 years and high surgical risk.
The primary endpoint was to assess all patients with severe symptomatic aortic stenosis at high surgical risk treated with TAVI. Also, to report on the procedural complications, and the mortality rates seen at the 30-day and 1-year follow-up. The secondary endpoints were rehospitalizations due to heart failure, valve restenosis, and symptom improvement using the NHYA scale.
No procedural complications were ever reported, and lack of mortality was seen at the 30-day or 1-year follow-up. Regarding patient readmission due to heart failure and valve restenosis, we should declare that any of the two events were reported. Symptom improvement in the NHYA scale functional class was maintained throughout the year.
TAVI is a safe and effective alternative for patients with severe symptomatic aortic stenosis at high surgical risk for conventional surgical aortic valve replacement as we saw in our cohort of patients.


***Keywords:*** *TAVI, severe aortic stenosis, endovascular treatment.*


## RESUMEN

La estenosis aórtica es la enfermedad valvular más frecuente en nuestro medio y en países occidentales. Se la considera como la tercera enfermedad cardiovascular, encontrándose solamente por detrás de la hipertensión arterial y la enfermedad coronaria.
Se realiza un estudio observacional retrospectivo de nuestros primeros casos con respecto al implante valvular percutáneo en posición aórtica (TAVI). Se incluyeron desde septiembre de 2018 hasta marzo de 2021 10 pacientes, de los cuales 8 (80%) eran mujeres (8 p), con un promedio de edad de 84 años y riesgo quirúrgico alto.
El objetivo primario fue valorar a todos los pacientes con estenosis aórtica severa sintomática de alto riesgo quirúrgico en los que se realizó TAVI, en función de las complicaciones asociadas al procedimiento, mortalidad a los 30 días y al año. Como objetivos secundarios se consideró la reinternación del paciente por insuficiencia cardíaca, reestenosis de la válvula y la mejoría sintomática del paciente utilizando la escala NYHA.
No hubo complicaciones asociadas al procedimiento; además, no se observó mortalidad a los 30 días y al año. Con respecto a la reinternación del paciente por insuficiencia cardíaca y reestenosis de la válvula, no se evidenciaron dichos eventos. La mejoría sintomática en su clase funcional se mantuvo a lo largo del año.
El TAVI es una alternativa segura y eficaz para aquellos pacientes con estenosis aórtica severa sintomática que tienen alto riesgo quirúrgico para la cirugía de reemplazo valvular convencional, como se demostró en nuestra cohorte de pacientes.


***Palabras clave:*** *TAVI, estenosis aórtica severa, tratamiento endovascular.*

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## INTRODUCTION

Aortic stenosis is the most common valvular heart disease in our region and in the Western countries. As a matter of fact, it is considered the third leading cardiovascular disease only behind arterial hypertension and coronary artery disease.
The prevalence of this disease is nearly 25% of the population > 65 years, and as high as 50% in patients > 80 years. [1]
The estimated mortality rate due to severe aortic stenosis in symptomatic patients is > 45% at the 2-year follow-up and up to 80% at the 5-year follow-up. [2] In the United States, the mortality rate due to aortic stenosis is 45% of the overall valvular heart diseases reported with increased mortality rates over the last 3 decades.[3]
The first transcatheter aortic valve implantation (TAVI) was performed by French Dr. Alain Cribier back in April 2002[4] in Rouen, France. At the beginning it was indicated for patients with symptomatic severe aortic stenosis associated with their underlying conditions, which elevated these patients' surgical risk complicating aortic valve replacement due to the high mortality rates reported.[6] In light of the successful data obtained by these studies, intermediate risk patients started to be included with similar results compared to conventional treatment.[6] Over the last few years, several studied including low surgical risk patients have been conducted with similar results compared to surgical aortic valve replacement (SAVR).[7]
The last iteration of the North American guidelines of 2020 on this issue recommends valve implantation in asymptomatic patients with severe aortic stenosis with LVEF < 50% and aged < 80 years. In these cases, the two options available are valve implantation or valve replacement based on the patient's past medical history (class I, level B). In symptomatic high-surgical risk patients with severe aortic stenosis, TAVI should be advised (Class I Level A).

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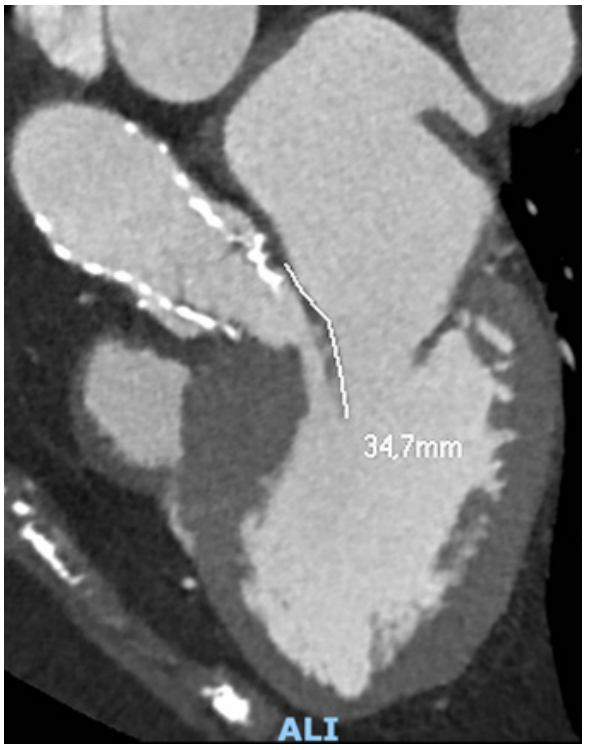


***Figure 1.*** *TAVI in patient with hypertrophic cardiomyopathy.The coronary computed tomography angiography shows the transcatheter aortic valve implantation of a patient with hypertrophic cardiomyopathy.*

In the European guidelines on the management of valvular heart disease of 2017, TAVI is advised in patients ineligible for surgical aortic valve replacement according to the heart team assessment (class I, level B).

In their last iteration, the Argentine clinical practice guidelines on the management of valvular heart disease and the last update from the 2019 consensus on transcatheter aortic valve implantation by the Argentine College of Interventional Cardioangiologists (CACI), TAVI is indicated for patients with symptomatic severe aortic stenosis considered ineligible for surgical treatment by the heart team. These are patients with possibilities of improving their quality of life and life expectancy in over a year despite the presence of comorbidities (class I, level B). Also, it is indicated for patients of high surgical risk with symptomatic severe aortic stenosis stratified based on the scores obtained in the American Association for Thoracic Surgery risk-calculator, EuroSCORE or ArgenSCORE and considered eligible candidates to surgery, but in whom the heart team prefers to indicate this treatment based on a risk-benefit ratio (class IIA, level B).

Over 50 000 implants were performed across the world over the first decade. In Argentina, the number of implants performed in 2019 was 664 (according to data from the Argentine College of Interventional Cardioangiologists-CACI-based on information disclosed from 150 different centers). In our center we have seen 10 cases 2 years after the creation of the unit.

This methodology confirmed a lower rate of major vascular complications (from 10% down to < 5%), [5] with an incidence rate of strokes between 2% and 3%. [5] However, although the requirement for pacemaker implantation is greater compared to surgical treatment (> 10% [5]) the endovascular treatment prompts quick patient recoveries.

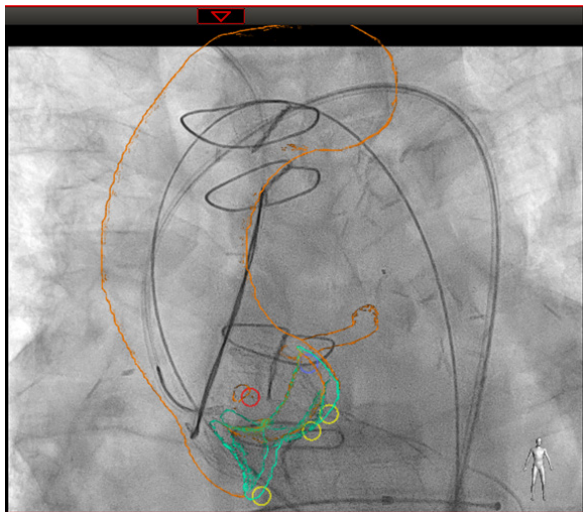

***Figure 2.*** *Stent-graft repositioning.CoreValve system repositioning using two snares for peripheral access.*

## METHODOLOGY

This was a retrospective and observational study that included, consecutively, from September 2018 through March 2021, patients with a diagnosis of symptomatic severe aortic stenosis (10 patients). Mean age was 84 years, a 100% of the patients had arterial hypertension (10 patients), 20% of them type 2 diabetes (2 patients), 30% had been treated with a previous valvuloplasty (3 patients), 20% with a previous biological aortic valve replacement (2 patients), 30% had heart failure (3 patients), 10% hypertrophic cardiomyopathy (1 patient), and 50% had coronary artery disease (5 patients) with EURO Score II values of 13.7, STS values of 14.6, and ArgenScore values of 31.6.

Valve implantation was performed by our interventional cardiologists. A routine echocardiogram and coronary angiography (Philips Azurion Clarity 7) were performed. Also, the tomographic protocol for TAVI (cardiac and vascular tomography) was followed using the Philips 128-channel CT scan for aortic disease and vascular access assessments. All patients received a transthoracic echocardiogram before and after the procedure.

Different types of CoreValve Evolut and Evolut - R (Medtronic Minneapolis, United States) or Acurate Neo devices (Boston Scientific) were used. Both devices consist of a valve built from a strong and flexible porcine pericardial tissue with a self-expandable nitinol frame. The diameter of the devices used were: CoreValve Evolut (23 mm and 29 mm), CoreValve Evolut – R (23 mm, 26 mm, and 29 mm), and Acurate Neo Device (medium size). All procedures were performed via transfemoral access.

In cases of "valve-in-valve" procedures, a CoreValve Evolut –R valve was implanted; in one patient with low origin of the coronary artery ostium it was decided to use the Acurate Neo Device Medium. There were no preferences regarding the type of valve used in the remaining cases.

One female patient had a past medical history of hypertrophic cardiomyopathy with alcohol septal ablation, and a 26 mm septum. She had been treated with a previous valvuloplasty with improvement of the gradients and further valve implantation (CoreValve Evolut - R).

**TABLE 1.** Baseline characteristics of the patients.

| | |
|---|---|
| Number of patients | 10 |
| Feminine sex | 8 (80%) |
| Age | 83.8 ± 3.73 |
| Body mass index | 29.2 ± 2.48 |
| Arterial hypertension | 10 (100%) |
| Type 2 diabetes | 2 (20%) |
| Dyslipidemia | 8 (80%) |
| Smoking habit | 7 (70%) |
| Peripheral vascular disease | 2 (20%) |
| Coronary artery disease | 5 (50%) |
| Coronary angioplasty prior to valve implantation | 5 (50%) |
| Previous AMI | 0 |
| Previous MRS | 1 (10%) |
| Heart failure | 3 (30 %) |
| Chronic AF | 2 (20%) |
| COPD | 3 (30%) |
| *Creatinine clearance levels* | 64.53 ± 16.6 |
| Previous pacemaker | 0 |
| Previous valvuloplasty | 3 (30%) |
| Previous SAVR | 2 (20%) |
| Hypertrophic cardiomyopathy | 1 (10%) |
| EuroScore II | 13.7 ± 3.41 |
| STS | 14.6 ± 6.45 |
| ArgScore | 31.6 ± 8.5 |
| LVEF | 58% |
| Stroke/TIA | 1 (10%) |
| Syncope | 1 (10%) |
| Angina | 6 (60%) |
| Dyspnea | 9 (90%) |
| NYHA Functional class | 3.3 ± 0.45 |

**TABLE 2.** Procedural results.

| Variable | |
|---|---|
| Successful valvuloplasty | 5 |
| Successful valve implantation | 10 |
| Type of valve implanted | |
| CoreValve *device* | 8 |
| 23 mm | 2 |
| 26 mm | 3 |
| 29 mm | 2 |
| Acurate Neo Device | 2 |
| Medium size | 2 |
| Delivery system | |
| Medtronic Enveo R Delivery | 4 |
| ACURATE TF Delivery | 2 |
| Medtronic Enveo PRO Delivery | 4 |
| Access route | |
| Transapical | 0 |
| Transfemoral | 10 |
| Right femoral access | 7 |
| Left femoral access | 3 |
| Cardiac pacing with PM | 7 |
| Surgical closure | 3 |
| Complications | 1 |
| Covered stent | 1 |
| Percutaneous puncture | 7 |
| Prostar XL | 2 |
| PROGLIDE | 5 |
| Predilatation during the procedure (True Flow) | 6 |
| Postdilatation | 4 |
| Aortic regurgitation > Grade 1 | 2 |
| Paravalvular leak > Mild | 3 |
| Paravalvular leak >Mild postdilatation | 1 |
| Valve embolization | 0 |
| Valve-in-valve | 2 |
| Coronary obstruction | 0 |
| Myocardial infarction | 0 |
| Ventricular perforation | 0 |
| Permanent pacemaker | 0 |
| Transient ischemic attack | 0 |
| Procedure-related death | 0 |
| Hospital stay, days | 5 |

The CoreValve Evolut and Evolut - R valves (Medtronic) were implanted using two different delivery systems: the Medtronic Enveo R Delivery System, and the Medtronic Enveo PRO Loading System. The Acurate Neo Device was implanted using the Acurate TF Tranfemoral Delivery System.

## PROCEDURE

Procedures were performed at a PCI-capable center with hybrid cath labs. A total of 90% of the patients were already on aspirin therapy. After implantation all patients remained on dual antiplatelet therapy (aspirin, and clopidogrel), except for patients with an indication for anticoagulation (for having a history of atrial fibrillation); these patients were treated with a single antiplatelet drug (clopidogrel) plus a vitamin-K antagonist.

During the procedure the patients received unfractionated heparin (100 IU/kg). All procedures were performed using IV sedation (dexmedetomidine, midazolam, fentanyl, and ketamine).

All vascular accesses were used via transfemoral approach. Eventually, they were closed percutaneously in 70% of the patients (7) (Prostar XL and Proglide), and surgically in 30% of the patients (3).

A true flow valvuloplasty perfusion catheter was used to predilate the aortic valve in 5 patients with severe calcification. The valve was implanted through fluoroscopy guidance and delivered using the appropriate technique. Immediate success was confirmed with the injection of supra-aortic contrast. A total 3 patients were postdilated due to moderate paravalvular leak. The patient treated with a valve-in-valve procedure was postdilated as well. One of the cases showed severe paravalvular leak due to low valve implantation. In this patient it was decided to reposition the valve via two different accesses (radial and femoral) using peripheral snares. A snare was used with the CoreValve Evolut device through retraction maneuvers and further implantation at aortic annulus level. The new control angiography performed confirmed the proper implantation of the valve, in this case, without any traces of paravalvular leak.

The techniques used to implant the CoreValve Evolut, Evolut – R, Acurate Neo Device valves are similar with different types of delivery systems. A 6-Fr introducer sheath was inserted through which a J-tip guidewire was advanced until it reached the aortic root. A pigtail catheter was mounted on such guidewire at valve level. Afterwards, an AL2 coronary guiding catheter was advanced, and the J-tip guidewire was removed. The guidewire was then exchanged for a straight guidewire with which the aortic valve effective orifice was crossed towards the left ventricle. It was then exchanged for a pigtail catheter and the pressures were measured. The catheter was advanced while mounted over the guidewire, which was later exchanged for a dedicated guidewire (Confida). Afterwards, an aortic valve mounted on a self-expandable stent was advanced through the guidewire and relea-

**TABLE 3.** Survival, symptoms, and echocardiographic findings.

| | Baseline | Post-operative | First echocardiogram |
|---|---|---|---|
| Survival | 10 | 10 | 10 |
| Symptoms (NYHA) | 3.3±0.45 | 1.3 ± 0.4 | 1.1 ± 0.31 |
| **Echocardiography** | | | |
| AVA ($cm^2$) | 0.68±0.12 | 1.5 ± 0.14 | 1.1 ± 0.1 |
| Peak gradient (mmHg) | 76.12 | 22 ± 5.5 | 22.71 ± 12.88 |
| Medium gradient (mmHg) | 40.88±13.14 | 12 | 14.5 ± 7.08 |
| LVEF (%) | 58±8.82 | 58.75 ± 9.9 | 52.6 ± 10.1 |
| Degree of aortic regurgitation | 0.7±0.64 | 1 ± 0.75 | 0.78 ± 0.79 |
| Degree of mitral regurgitation | 0.7±0.8 | 1 ± 0.75 | 0.9 ± 0.6 |

sed at aortic valve annulus level simultaneously with transient pacemaker cardiac pacing (7 patients).

### ENDPOINTS

To assess all patients of high surgical risk with symptomatic severe aortic stenosis treated with TAVI based on the complications associated with the procedure (stroke, definitive pacemaker, and major bleeding), as well as the 30-day and 1-year mortality rates.

The study secondary endpoints were patient rehospitalizations due to heart failure, valve restenosis, and symptom improvement using the NHYA Functional Classification.

### STATISTICAL ANALYSIS

All clinical, demographic, and technical data were collected and became part of a database at the unit. All data were analyzed statistically using a software available on the market (Statistica R, version 8.0). All data were expressed as mean ± standard deviation or as percentage, when appropriate.

## RESULTS

From September 2018 through March 2021 a total of 10 patients were included. A total of 80% were women (8 patients) with a mean age of 84 ± 3.7 years, 100% had arterial hypertension (10 patients), 20% had type 2 diabetes (2 patients), 20% had peripheral vascular disease (2 patients), 30% had been treated with a previous valvuloplasty (3 patients), 20% with aortic valve replacement (2 patients), 50% had coronary artery disease treated with angioplasty prior to valve implantation (5 patients), 30% had heart failure (3 patients) with the following surgical risk scores: EURO Score = 13.7 ± 3.41, STS = 14.6 ± 6.45, and ArgenScore. (See table 1).

Valve implantation was performed in 100% of the patients (10 patients). All of them were performed via transfemoral access. A total of 30% of the patients received the CoreValve Evolut device (3 patients), 50% received the CoreValve Evolut – R, and 20% the Acurate Neo Medium device (2 patients). Percutaneous closure with the Proglide SMC System was used in the last 5 patients. (See table 2).

The first percutaneous closure procedure became complicated due to incomplete closure (the Prostar XL was used) at suture level confirming the presence of leak that required endovascular repair with a covered stent.

The mean hospital stay was 5 days, but it could have been shorter because one of the patients had fractured his hip prior to stent-graft implantation. The hip fracture was already on the surgical plan and a decision was made to perform the valve implantation first and then proceed to replace the hip.

Clinical follow-up was performed 1 month after the procedure (with further controls), and the ECG control was performed, on average, 3 months after the procedure.

The procedural complications were stroke (incidence rate: 0%), major bleeding requiring transfusions (incidence rate: 0%), and acute kidney injury requiring dialysis (incidence rate: 0%). As part of the implantation procedure, all patients received a preventive transient pacemaker, but none of them a definitive pacemaker.

The postoperative 30-day and 1-year mortality rates were 0% and 0%, respectively. Also, 2 non-cardiac deaths were reported after 1 year that were associated with COVID-19.

The rates of rehospitalizations due to heart failure and valve restenosis were 0% and 0%, respectively (peak gradient, 22.7, AVA 1.1, LVEF, 52%) while symptom improvement based on the NYHA Functional Class dropped from 3.3 to 1.1, and was maintained throughout the year.

## DISCUSSION

Our heart team has been performing transcatheter aortic valve implantation procedures since this procedure became available and, therefore, have been gaining experience and acquiring a learning curve without major complications.

Procedures were assisted by a proctor based on the valve implanted.

Based on the results obtained, TAVI proved to be a safe an effective procedure in our center for patients with symptomatic severe aortic stenosis at high risk of cardiovascular surgery based on risk scores that predict a theoretically high mortality rate for patients who would be eligible for cardiovascular surgery like the EUROScore (13.7), the STS (14.6), and the ArgenScore (31.6). The actual mortality rate associated with TAVI in our unit was 0%.

All former studies [6] that assessed this procedure in high-risk patients were conducted in a non-pandemic setting. Because this study was conducted during the pandemic we should see whether this variable impacts or not such results.

## CONCLUSIONS

Transcatheter aortic valve replacement is a safe and effective alternative to surgical aortic valve replacement for patients of high surgical risk with symptomatic severe aortic stenosis. [5]

In our cohort of patients, none of the usual complications associated with the procedure were reported. As a matter of fact, the 30-day and 1-year mortality rates were 0 %.

With the data obtained from these conclusions, the technological advances made, and the scientific studies conducted on this regard, in these patients, risk stratification should help us determine the adequacy and ultimate indication of the endovascular strategy. Over 50 000 implants were performed over the first decade worldwide. In Argentina, in our center, we have seen 10 cases 2 years after the creation of the unit.

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