Experience with Percutaneous Aortic Valve Implantation in Patients with Severe Aortic Stenosis at High Surgical Risk in a Rural Community

Surgical aortic valve replacement is the treatment of choice for severe, symptomatic aortic stenosis. Occasionally, surgery is impossible due to old age and comorbidities. In these cases, percutaneous valve replacement is a safe and effective option for high risk patients.

The purpose of this article is to describe the experience of a consolidated working team on transcatheter aortic valve implantation (TAVI) carried out in a rural city center that admits patients from the same city or from neighboring rural towns after having systematized the technique, with follow-up until the study cutoff date.

This prospective registry was initiated after the initial experience carried out between 2013 and 2016, and after each one of the 4 interventional cardiologists obtained the certification to perform the procedure. Patients were assessed by a multidisciplinary team of clinical cardiologists, echocardiography specialists, electrophysiologists, interventional cardiologists, cardiac surgeons, and anesthesiologists. Fifty-one consecutive high-surgical risk patients with symptomatic severe aortic stenosis ruled out for conventional surgery, who underwent TAVI between 12/01/2016 and 04/30/2019 in a rural community clinic, were included.

Mean age was 78 6.1 years, and 37.2% were men. Mean-valve area measured by Doppler ultrasonography was 0.67±0.27 cm2. In 92.2% of cases, patients were in functional class (FC) III, and in 7.8% in FC IV. The EuroSCORE was 15.4±7.5 (Table 1). Table 1 shows patient characteristics. All the procedures were performed under deep sedation and local anesthesia. One patient required mechanical ventilation for 48 hours following the procedure due to respiratory depression. Dissection of the femoral artery was performed in all the procedures, and in 49 of the 51 cases an active fixation catheter was placed for the transient pacemaker and in the remaining 2 the stimulus was performed by the valve guidewire. In 50 cases (98%), self-expanding valves were implanted, while in the remaining case, a balloon-expandable valve was used. All the procedures were successful, resulting in a significant reduction of the aortic transvalvular peak gradient (71±19 mm Hg to 5±3 mm Hg; p <0.001), without development of moderate or severe post-procedure aortic regurgitation. The size of the implanted valves and the requirements of pre-or post-valve implantation valvuloplasty are described in Table 2.

Baseline ECG showed sinus rhythm in 46 patients. The remaining 5 patients presented with atrial fibrillation (9.8%). After the procedure, 21 patients presented with complete left bundle branch block (CLBBB) (41.2%) and 9 required implantation of a permanent pacemaker (17.6%) (8 due to intraprocedural complete atrioventricular block (CAVB), and 1 due to CLBBB with first-degree atrioventricular block (AVB) with prolonged HV interval). One patient required pericardial drainage due to signs of cardiac tamponade 24 hours after the procedure. Median length of hospital stay was 3 days (IQR 25-75: 2-5 days) (Table 2). No deaths occurred during the procedure or hospitalization. Follow-up after discharge was at 15 and 30 days, and at 6 months in the doctor's office, where a complete physical examination was performed and the evolution, symptoms, FC and control ECGs at 30 days and 6 months were evaluated. Follow-up during the evolution was coordinated with the primary cardiologist of the patient's home town. In addition to the scheduled visits, a telephone follow-up was carried out in which survival, hospitalization, intercurrences, and FC were recorded. Three deaths from non-cardiac cause occurred during follow-up. Median follow-up was 431 days (IQR 258-595 days). Six patients had to be hospitalized during follow-up: 3 for dyspnea, 1 for pseudoaneurysm at the site where the arterial introducer was placed (contralateral to the dissected artery), 1 for infection at the surgical site, and 1 for syncope.

Table 1. Baseline population characteristics

Age (years)	78 ± 6.1
Female sex % (n)	62.8% (32)
Logistic EuroSCORE	15.4 ± 7.5
NYHA III dyspnea % (n)	92.2 (47)
NYHA IV dyspnea % (n)	7.8 (4)
Coronary heart disease % (n)	62.7 (32)
Previous cardiac surgery % (n)	5.9 (3)
Diabetes % (n)	19.6 (10)
Peripheral vascular disease % (n)	82.3 (42)
COPD % (n)	29.4 (15)
Renal dysfunction % (n)	51 (26)
Pulmonary hypertension % (n)	52.9 (27)
History of thoracic radiation % (n)	5.9 (3)
History of aortic valve replacement	9.8 (5)
Atrial fibrillation % (n)	9.8 (5)
Ejection fraction	47.7 ± 18 %
Ejection fraction 30% - 50%	43.1 (22)
Ejection fraction <30%	9.8 (5)
Aortic valve area (cm2)	0.67 ± 0.27
Mean gradient (mmHg)	45 ± 16
Maximum gradient (mmHg)	71 ± 19

NYHA: New York Heart Association. COPD: Chronic obstructive pulmonary disease.

Table 2. Procedure and patient follow-up

PROCEDURE (N= 51)	
Anesthesia: Local anesthesia or conscious sedation, % (n)	100 (51)
Mortality, % (n)	0
Cardiac tamponade, % (n)	2% (1)
Stroke, % (n)	0
Vascular complications, % (n)	3.9% (2)
Hospitalization (days), median (IQR 25-75)	3 (2-5)
Post-TAVI maximum gradient (mmHg)	5 ± 3 mm
Aortic regurgitation	
0, % (n)	62.7 (32)
I, % (n)	35.3 (18)
II, % (n)	2 (1)
III-IV, % (n)	0
Permanent pacemaker implantation, % (n)	17.6 (9)
Requirement of valvuloplasty prior to valve replacement, % (n)	60.8 (31)
Requirement of valvuloplasty after valve replacement, % (n)	23.5 (12)
No requirement of valvuloplasty in valve implantation, % (n)	35.2 (18)
Prosthetic valve size	
#23, % (n)	2 (1)
#25/26, % (n)	39.2 (20)
#29, % (n)	50.9 (26)
#31, % (n)	5.9 (3)
#34, % (n)	2 (1)
Prosthetic valve type	
CORE-VALVE, % (n)	27.4 (14)
CORE-VALVE EVOLUT R, % (n)	60.8 (31)
SAPIEN XT, % (n)	2 (1)
ACURATE neo/TF, % (n)	7.8 (4)
PORTICO, % (n)	2 (1)
FOLLOW-UP	
Follow-up (days), median (IQR 25-75)	431; (258-595)
NYHA I, % (n)	90.2 (46)
Post-TAVI valve area (cm2)	1.82 ± 2
Post-TAVI mean gradient (mmHg)	8.3 ± 5
Mortality, % (n)	5.9 (3)
Hospitalizations, % (n)	11.8 (6)

NYHA: New York Heart Association. TAVI: Transcatheter aortic valve implantation

Improvement in FC was observed in all patients during follow-up, with progress to FC I in 90.2% of cases (Table 2). In our case, results were consistent with other national registries. (1) The absence of mortality, the success of all the procedures and the significant improvement in patient FC support our conclusion. The need to provide adequate medical care poses a dilemma to institutions in rural areas, which must assume greater challenges, with a demand for better results based on a historical perception of lower performance in procedures requiring more technology in these areas. These results were achieved due to the systematization of the procedure and the team expertise. In addition to a short hospital stay (median 3; IQR 2-5 days), the cost-benefit analysis of performing this type of procedure in the patient's town or in neighboring cities could also be considered favorable, since it allows patients to remain in their environment, in permanent contact with the attending physician in charge of their follow-up, and also prevents their family members travel expenses and higher costs for lodging and meals in larger cities. (2) Aortic valve replacement under local anesthesia or conscious sedation, avoidance of orotracheal intubation, procedure systematization and patient follow-up are also associated with the short hospital stay. (3)

Regarding the acute intercurrences derived from the procedure, 9 patients required implantation of a permanent pacemaker due to conduction disorders, and 1 patient required drainage due to cardiac tamponade. With the evolution of implantable devices, the trend for pacemaker use has been decreasing both in published registries and in our series, where pacemaker implantation was required in 3 of the last 25 patients (12%). (4) The use of premeasured chordal loops is a very important factor in preventing cardiac tamponade, an intercurrence observed in only one case of our series. In this regard, active fixation pacemaker leads or guidewires are also convenient.

A significant improvement in patient FC was detected during follow-up, with 3 deaths (5.9%) from non-cardiac cause. The information on long-term follow-up of patients undergoing percutaneous aortic valve implantation available in the literature is limited. Mortality rate at 5 years ranges between 50%-70%. (5, 6) According to published data, the highest mortality rate occurs in the first follow-up year, at the expense of the first month, due to complications derived from the procedure. (6) After hospital discharge, the main cause of death is non-cardiac, due to the comorbidities in this population. (5, 6) Since no mortality was associated with the procedure in our series, long-term follow-up of this population is important in order to quantify survival and determine the causes of death.

In conclusion, treatment of severe aortic stenosis with percutaneous valve replacement in high surgical risk patients – who were ruled out for conventional surgery –is a feasible alternative in patients from a rural community. The adequate selection of our patients, the systematization of the procedure technique, and a multidisciplinary approach increase its effectiveness and safety.

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Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material).

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Federico Blanco[1], Rodrigo Blanco[1], Mauricio Bonet[1], Gustavo Iralde[2], Mariano Campeni[3], Alejandro García Escudero[1]

[1] Department of Interventional Cardiology, Cardiovascular Chivilcoy

[2] Department of Electrophysiology, Cardiovascular Chivilcoy

[3] Department of Cardiovascular Surgery, Cardiovascular Chivilcoy

Federico Blanco - Cardiovascular Chivilcoy - Av. Soarez 321- (6620) Pcia. de Buenos Aires - E-mail: federicoblanco@ymail.com

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Intoxication with Psychotropic Drugs and Indication for ECMO

This is the case of a 25-year-old female patient with a history of several autolytic attempts due to drug intoxication, the latest resulting in hospitalization in the Critical Care Unit in December 2016.

On June 25, 2016, at 10 pm, the patient was taken by her mother to the Emergency Room; since she was admitted with Glasgow 4/15, orotracheal intubation (OTI) and mechanical ventilation were performed. A nasogastric tube was inserted and gastric lavage was performed, removing some tablets, and treatment by serial activated charcoal in combination with laxatives was initiated.

A friend of the patient mentioned that she had ingested a great number of tablets early in the morning. A blister of medications was provided: alprazolam 30 mg, amitriptyline 1,250 mg, valproic acid 7,500 mg, and pregabalin 1,500 mg. ECG and lab tests on admission were normal. The plasma concentration of valproic acid was 309 μg/m, and chest x-ray showed an image consistent with bronchoaspiration.

On June 28, 2016, the patient presented with cardiopulmonary arrest due to ventricular fibrillation and cardiopulmonary resuscitation was performed for 20 minutes. The patient progressed with distributive and cardiogenic shock, requiring high doses of vasoactive drugs.

In view of shock refractoriness, A-V ECMO (Extracorporeal Membrane Oxygenation) for systemic assistance was indicated, reducing the inotropic support and showing slow improvement. On the third day of ECMO support, the patient showed improvement and was progressively weaned from ECMO, which was removed on day 4. Then, mechanical ventilation was removed on day 5, after a short weaning period.

EMCO is a standard technique for the treatment of refractory cardiogenic shock and cardiac arrest induced by drug intoxication. (1) Cardiac arrest may occur during the course of intoxication with psychotropic drugs. Awareness of the severity of a toxic cardiac arrest should allow shortening the times of ECMO indication and placement before the cardiac arrest occurs.

ECMO is a therapeutic tool in cardiotoxicity due to tricyclic antidepressants, since it is a short-term ventricular assist device with easy placement and weaning which provides hemodynamic and systemic support. (2) It also allows the reduction or discontinuation of inotropic agents that perpetuate cardiotoxicity.

The toxic dose of amitriptyline is >5mg/kg; a dose between 10 and 20 mg/kg results in severe toxicity, and >25 mg/kg is lethal. Amitriptyline causes sinus tachycardia, hypotension, ventricular tachycardia and

Fig. 1. ECMO used during patient treatment.