Late Survival of Aortic Valve Replacement in a Community Hospital

Long-term outcomes of aortic valve replacement are the best standard of quality to compare new techniques of endovascular prosthesis implantation. A recent study on surgical patients aged 55-65 years showed that actuarial 15-year survival of traditional aortic valve replacement was 46.4% in the biological valve group versus 60.6% in the mechanical valve group. (1) Another study, this time on patients aged >70 years, revealed that the 10-year survival was 46.1% with mechanical and 57.8% with biological prostheses, with major bleeding rates of 37.0% and 18.8%, respectively. (2)

Given that there are not many local studies with more than 10 years of follow-up, the purpose of this study was to analyze the 20-year overall survival and cardiovascular event-free survival of aortic valve replacement in a community hospital with electronic medical records. Late outcomes of isolated aortic valve replacements or combined with coronary artery by-pass grafting, operated on between 1999 and 2002 in a community hospital, were retrospectively studied. The 20-year follow-up was done through the institution's electronic medical records and telephone contact. Since it was mostly a population of patients affiliated with the hospital, a high followup rate could be obtained. Baseline data at the time of surgery were included, and cardiovascular events (myocardial infarction, stroke, major bleeding or prosthetic dysfunction) as cause of death were considered. Long-term all-cause and cardiovascular mortality were evaluated. Follow-up was analyzed with Kaplan-Meier curves, and comparisons were made with the log-rank test. Continuous variables were expressed as mean \pm standard deviation (SD) or standard error (SE). Among 80 aortic patients undergoing surgery, a mean follow-up of 94 months (SE 9.6) (range 6-253) was achieved in 63 of them (79%). Follow-up of 496 patient-years was obtained with 4.8% annual risk of all-cause death. Mean age at the time of surgery was 70.3 years (SD 8.4), and 60% were male patients. A total of 44% mechanical prostheses were used -the rest were biological prostheses-, whose sizes were n19, n21, n23, and n25 or larger in 21%, 35%, 25% and 19% of cases, respectively. Overall survival at mean follow-up was 0.691 (SE 0.07), 0.467 (SE 0.09) at 15 years and 0.389 (SE 0.10) at 20 years (Figure 1), whereas, considering cardiovascular mortality alone, survival at mean follow-up was 0.855 (SE 0.05) and 0.658 (SE 0.10) at 15 years and 20 years (log-rank p = 0.042) (Figure 2). In turn, cardiovascular event-free survival at

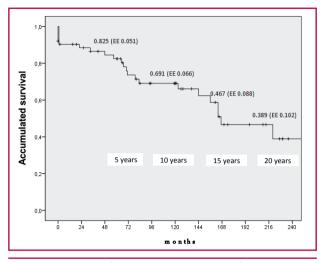


Fig. 1. Late survival from all-cause mortality of single or combined aortic valve replacement.

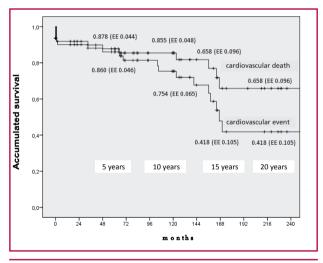


Fig. 2. Late survival from cardiovascular and cardiovascular event-free mortality (death, infarction, stroke, major bleeding, or prosthetic dysfunction) of single or combined aortic valve replacement.

mean follow-up time was 0.814 (SE 0.05) and 0.418 (SE 0.11) at 15 years and 20 years (Figure 2). Total follow-up revealed 4% prosthetic dysfunction, 16% gastrointestinal bleeding or stroke, but no prosthetic endocarditis.

Over the past decade, several local studies have published long-term survival outcomes from aortic valve surgery, although none of them exceeded 7 years of follow-up. Overall survival rates of 94.8%, 88.6%, 85%, and 82.4% were reported at 1, 3, 5, and 7 years, respectively, for aortic valve replacements with biological prostheses. Considering only death of cardiac origin, survival rates in those periods rose to 97.2%, 94.6%, 91.2%, and 89.4%. (3) In patients >80 years, those same authors found that survival at the first year was 98.6%, at three years 87.65%, at 5 years 77.3%, and at 7 years 48.6%. (4) Also in octogenarians, another local study showed survival rates of 88% at one year, 85% at two years, and 69% at six years. In turn, when patients were divided into low and intermediate risk, the 5-year survival rate was 88.5% and 67.8%, respectively. (6) In comparison, our results on cardiovascular deaths were similar to those published by other local centers.

In conclusion, complete electronic records of community hospital affiliates operated on more than 15 years ago allowed for the analysis of overall and eventfree long-term survival of aortic valve replacement. These results will serve as evidence for decision making in the surgical management of aortic valve disease, and as a standard when choosing between surgery and percutaneous valve implantation.

Conflicts of interest

None declared.

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Osvaldo M. Tenorio Núñez, Michel David, Julio C. Giorgini, José María Álvarez Gallesio, Claudio C. Higa, Raúl A. Borracci

Department of Cardiology and Department of Cardiac Surgery, Herzzentrum, Hospital Alemán, Buenos Aires. Av. Pueyrredón 1640, (C1118AAT), Buenos Aires, Argentina. e-mail: omtenorio@hotmail.com

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Cardiovascular health status in 3,168 outpatients attended for the first time in a Cardiovascular Center of Guayaquil - Ecuador from 2012 to 2018

Cardiovascular diseases are the leading cause of morbidity and mortality worldwide, and particularly in low-income countries it contributes to increase death rates despite the lower risk-factor burden compared with high-income countries. (1) In Latin America, cardiovascular diseases represent billions of dollars in hospitalization and healthcare costs annually. (2)

Because of epidemiological transition, diseases such as Chagas disease or rheumatic valve disease have been replaced by other non-communicable chronic diseases. (3) Cardiovascular risk factors among the general population are highly prevalent, and reducing its burden would result in reduction of cardiovascular events. (4, 5) However, ideal cardiovascular health in Latin America is not as good as desired. (6)

Therefore, we aim to determine the cardiovascular health status in ambulatory patients who consult in a single cardiology center of Guayaquil, Ecuador.

Records of outpatients attended from 2012 to 2018 in a single cardiology center were reviewed. Clinical profile, comorbidities as well as demographics were extracted from medical records. Patients aged 18 or older were included in the analysis, and those with incomplete data were excluded. Redundant files were also excluded.

Categorical data were presented as frequencies and percentages, and compared using the chi square test. Numerical data were expressed in terms of mean with standard deviation, and compared between groups using ANOVA or the Kruskal-Wallis test. All statistical analyses were carried out using SPSS 24 software.

A total of 5,135 patients were attended from 2012 to 2018. Among these, 1,296 were excluded because of incomplete data and 671 for redundant data. After exclusion, 3,168 patients were included for the analysis. Mean age was 54 ± 18 years and 40.6% were male (See Table). The body mass index revealed that 40.2% were overweight and that only 29.2% had normal BMI.

Mean abdominal circumference was 91.6 ± 14.2 cm, and 65.4% had abdominal obesity defined as ≥ 102 cm in men and ≥ 88 cm in women.

Prevalence of cardiovascular risk factors were as follows: hypertension (defined as $\geq 140/90$ mmHg) 38.5%; diabetes 8.9% and dyslipidemia 27.9%. All these risk factors were associated with increasing age.

Heart failure (HF) was present in 2.3% of patients and coronary heart disease (CHD) in 5.1%. Other less common comorbidities were atrial fibrillation (1.7%), stroke/TIA (0.9%) and chronic kidney disease (CKD) (4.5%). As described with cardiovascular risk factors, the prevalence of all these comorbidities increased with aging.

Unhealthy habits such as smoking, alcohol abuse, poor diet and lack of physical activity were found in 7.4%, 2.1%, 7.9%, and 10.7% of patients, respectively.

Table. Cardiovascular risk factors and morbidities of included patients. CHD: coronary heart disease. AF: atrial fibrillation. CKD: chronic kidney disease. TIA: Transient ischemic attack.

Male, n (%) Age (years), mean ± SD Weight (kg), mean ± SD Height (cm), mean ± SD BMI (Kg/m2), mean ± SD Abdominal circumference, mean ± SD Abdominal obesity, n (%) Hypertension, n (%) Diabetes, n (%)	Total sample (N = 3,168)	1st Quartile (n=850)	2nd Quartile (n=766)	3rd Quartile (n=754)	4th Quartile (n=798)
Weight (kg), mean ± SD Height (cm), mean ± SD BMI (Kg/m2), mean ± SD Abdominal circumference, mean ± SD Abdominal obesity, n (%) Hypertension, n (%)	1287 (40.6)	295 (34.7)	327 (42.7)	345 (45.8)	320 (40.1)
Height (cm), mean ± SD BMI (Kg/m2), mean ± SD Abdominal circumference, mean ± SD Abdominal obesity, n (%) Hypertension, n (%)	54 ± 18	32 ± 6	48 ± 4	61 ± 4	78 ± 8
BMI (Kg/m2), mean ± SD Abdominal circumference, mean ± SD Abdominal obesity, n (%) Hypertension, n (%)	74 ± 17.4	72.5 ± 19.7	77 ± 17.8	77 ± 16.3	69.7 ± 14.1
Abdominal circumference, mean ± SD Abdominal obesity, n (%) Hypertension, n (%)	162.1 ± 10.1	164.4 ± 9.5	164.3 ± 9.8	162.5 ± 9.7	157.3 ± 9.7
Abdominal obesity, n (%) Hypertension, n (%)	28 ± 5.4	26.6 ± 5.8	28.4 ± 5.2	29.1 ± 5.2	28.1 ± 4.9
Hypertension, n (%)	91.6 ± 14.2	86 ± 15.1	91.9 ± 14.2	94.8 ± 13.4	94.2 ± 11.9
	2072 (65.4)	390 (45.9)	499 (65.1)	575 (76.3)	608 (76.2)
Diabetes, n (%)	1221 (38.5)	110 (12.9)	211 (27.5)	354 (46.9)	546 (68.4)
	283 (8.9)	12 (1.4)	38 (5)	96 (12.7)	137 (17.2)
Dyslipidemia, n (%)	884 (27.9)	93 (10.9)	187 (24.4)	279 (37)	325 (40.7)
Heart failure, n (%)	73 (2.3)	3 (0.4)	3 (0.4)	11 (1.5)	56 (7)
CHD, n (%)	160 (5.1)	7 (0.8)	11 (1.4)	36 (4.8)	106 (13.3)
AF, n (%)	54 (1.7)	3 (0.4)	3 (0.4)	12 (1.6)	36 (4.5)
CKD, n (%)	143 (4.5)	3 (0.4)	11 (1.4)	28 (3.7)	101 (12.7)
Stroke/TIA, n (%)	27 (0.9)	0	0	6 (0.8)	21 (2.6)
Smoking, n (%)	233 (7.4)	40 (4.7)	40 (5.2)	78 (10.3)	75 (9.4)
Alcohol, n (%)	67 (2.1)	23 (2.7)	15 (2)	13 (1.7)	16 (2)
Poor diet, n (%)	250 (7.9)	38 (4.5)	63 (8.2)	74 (9.8)	75 (9.4)
Sedentarism, n (%)	339 (10.7)	60 (7.1)	80 (10.4)	92 (12.2)	107 (13.4)

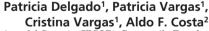
To our knowledge, this is the first study in ambulatory patients of Guayaquil, Ecuador, that aims to describe cardiovascular health status in adults. The main strength of this research is the long term followup and sample size. The main limitations are its retrospective design and selection bias derived for using data from one single center.

In conclusion, cardiovascular health still needs to be improved in adults of Ecuador in order to decrease the cardiovascular disease burden.

Conflicts of interest

None declared.

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¹ Instituto Ecuatoriano del Corazón (IECOR), Guayaquil - Ecuador ² Universidad de Especialidades Espíritu Santo, Guayaquil - Ecuador Email: pdelgadodevargas@gmail.com

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Percutaneous Management of Prosthetic Valve Dysfunction in Mitral Position: Transapical Mitral Valve-In-Valve Implantation

Resolution of mitral valve dysfunction has been an important issue in cardiac surgery for many years. The mitral valve complex is altered by several conditions that involve the leaflets, the annulus and the papillary muscles. Medical advances have decreased rheumatic causes and degenerative ones are now predominant, particularly in developed countries.

Since the 1960's, mechanical and biological valve prostheses and various mitral valve repair techniques have been developed. Nowadays, with the significant advances in cardiovascular medicine, indications have extended and widened the universe of treated patients, resulting in considerable life extension, (1) as very few patients with severe MR (mitral regurgitation) survive in the long-term without intervention. (2) The transfemoral implantation of an aortic valve made by Cribier in 2002 and the first transapical mitral valve-in-valve implantation made by Cheung in 2009 (3) are two samples of creativity in interventional cardiology to solve a key cardiac issue, avoiding the use of extracorporeal circulation and wide chest opening.

This technique has been used mainly with bioprosthetic valves in aortic position, not so commonly in mitral position, and even less in the tricuspid valve. (4) Techniques that require an intense learning phase can achieve better results in high-volume, high-experienced hospitals. (5) Moreover, heart valve centers should have structured training programs. (4)

The purpose of this presentation is to introduce the first transapical mitral valve-in-valve implantation in Argentina. We describe the case of an 83-year old woman with previous myocardial infarction in 2008. She underwent combined surgery in 2009 with biological mitral valve number 25 (biological porcine valve HVP) implantation together with aorto-coronary venous bypass to the anterior descending aorta, and aorto-coronary venous bypass to the lateral ventricular circumflex artery. The patient suffered from chronic atrial fibrillation under anticoagulation therapy and chronic renal failure with creatinine clearance of 32 mL/min.

She also had functional class II dyspnea, which had progressed to functional class III in the last few months. Transthoracic echocardiography (TTE) showed severe mitral regurgitation with eccentric jet with Coanda effect to the atrial roof, and marked collapse of both leaflets. She had severe tricuspid regurgitation with pulmonary artery systolic pressure (PASP) of 75 mmHg, mild to moderate left ventricular systolic function (LVSF) with ejection fraction (EF) of 50% and inferior, inferolateral, and septal akinesia. The coronary angiography showed moderate lesion in the left main coronary artery, severe lesion in the anterior descending artery and in the circumflex artery, and total occlusion of the right coronary artery; both venous bypasses were occluded. The case was discussed in the clinical-surgical seminar of the Department of Cardiology, in which it was decided to

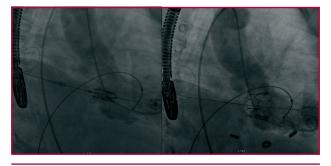


Fig. 1. Fluoroscopy with SAPIEN XT valve in mitral position before deployment (left) and after deployment (right).

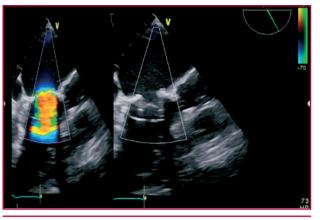


Fig. 2. SAPIEN XT valve in mitral position; evaluation with transesophageal echocardiography with Doppler (left) and without Doppler (right).

perform a percutaneous valve-in-valve implantation in mitral position, and to include the patient in the institutional structural heart disease program.

The intervention was performed under general anesthesia, and supported by transesophageal echocardiography (TEE), ruling out the presence of thrombus. A minithoracotomy at the level of the fifth/sixth left anterior intercostal space was performed, followed by pericardial opening maintained with two stitches with triangular concentric prolene 3-0 sutures. A direct puncture of the apex was performed, and a soft guidewire was advanced and exchanged for a 0.035" ExtraStiff guidewire in the left atrium. The procedure was confirmed mainly with TEE, since the implanted biological valve did not provide radiolucent edges as guidance for correct positioning. (6). Proper position of the Edwards SAPIEN XT balloon-expandable valve number 26 (Figure 1) was done indirectly via a pig tail catheter in the left ventricle, and through rapid pacing at 180 beats per minute; the balloon was expanded and the valve was deployed. The procedure was successfully completed after assessing correct valve functioning monitored by radioscopy, MUGA scan, and TEE, with absence of paravalvular leaks (Figure 2). The patient was transferred to the coronary care unit, and was discharged 4 days after surgery without complications.

Follow-up TTE prior to discharge and one-month post-intervention showed normal functioning of the prosthesis with adequate gradients.

Postoperative and 1-month clinical follow-up revealed evident clinical improvement in functional class I. The TTE performed 5 months afterwards revealed slightly depressed left ventricular systolic function with EF of 48%, lateral and inferolateral akinesia, preserved right ventricular size and slightly depressed function with TAPSE (tricuspid annular plane systolic excursion) of 17, moderate left atrial enlargement, normal function of the mitral valve prosthesis, moderate tricuspid valve regurgitation with 60 mmHg PASP, sinus rhythm in all controls, and functional class I. Transapical mitral valve-in-valve implantation is an effective and safe procedure in high-risk patients in whom surgery is contraindicated. The current approach, with almost no restrictions on indications, confronts us with a large number of patients who represent a great challenge for their treatment due to age, comorbidities, ventricular and prosthetic dysfunction, etc. Risk scores greatly contribute to the indications and restrictions of surgical procedures. This may determine an extreme limit and discourage a conventional surgical procedure, as in the case described.

The purpose of our presentation was to demonstrate that this procedure is feasible in our context, and our outcomes are of high medical quality.

Mid- and long-term follow-up of patients undergoing this technique is necessary, although the initial evidence shows a favorable and encouraging panorama in this type of patients.

Current experience with percutaneous mitral valve replacement techniques is very scarce, and surgical mitral valve repair techniques have demonstrated a higher benefit over valve replacement, in part due to the preservation of the chordae tendineae and papillary muscles. (6)

With the advent of new bioprostheses, percutaneous mitral valve replacement will have an exponential growth; after the initial stage of the first experiences, feasibility and safety of these valves will have to be demonstrated and supported by randomized studies to determine their prognostic value in the treatment of mitral valve disease.

The development of minimally invasive procedures requires state-of-the-art technology, since it is impossible to develop this type of program without excellent resources. We are certain these procedures will be progressively used by all health centers in Argentina.

Conflicts of interest

None declared.

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> Juan R. Alderete^{1, 2}, Alberto C. Anaya Revolledo^{1, 2}, Verónica I. Volberg², Miguel Rubio³, Gustavo E. Barrera^{1, 2}, Sara Berensztein² 1 Catheterization Laboratoriy. Hospital de Clínicas José de San Martín 2 Department of Cardiology. Hospital de Clínicas José de San Martín 3 Department of Cardiovascular Surgery. Hospital de Clínicas José de San Martín

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Refractory Neonatal Atrial Flutter

Atrial flutter (AFl) is a rare tachyarrhythmia that may occur in utero or on the first few days after birth, with a frequency of atrial contraction (saw-tooth P waves) ranging from 280 to 450 beats per minute (bpm). It accounts for about 32% of all neonatal arrhythmias and it may be asymptomatic or present with severe heart failure. Both the immature myocardium and the high pressures in the right atrium during the perinatal period are factors that may promote atrial re-entry, causing flutter in the fetus or the neonate. In general, AFl is not associated with structural heart disease, and treatment should consider the use of antiarrhythmic drugs or synchronized cardioversion. (1-3)

We describe the case of a full-term male neonate. large for his gestational age (3875 g), delivered by a 27-year-old multigravida woman, born by emergency C-section due to fetal tachycardia diagnosed hours before delivery. On admission to the NICU, the baby presented with a heart rate (HR) of 214 bpm. ECG showed saw-tooth P waves suggestive of AFl with a 2:1 conduction pattern (atrial frequency: 375 bpm, ventricular frequency: 214 bpm). Chest X-ray revealed cardiomegaly (Figure 1A & B), and echocardiography reported systolic dysfunction (EF: 58%), with no structural heart disease. The patient was started on intravenous amiodarone (loading dose: 5 mg/kg), and then in continuous infusion (5 ug/kg/min) for 12 hours with no positive response, so the amiodarone dose was increased to 10 ug/kg/min. A second ECG reported no variations, therefore cardioversion at 1 joule/kg was performed on two continuous occasions (2-min interval) and sinus rhythm was achieved (Figure 2). Amiodarone infusion was administered for three more days, and then propranolol therapy was started (2 mg/ kg/day). A new echocardiography reported mild pulmonary hypertension (36 mmHg) and thus sildenafil was added (4 mg/kg/day). Serology was negative for HIV, VDRL, and TORCH. Thirteen days after birth, the patient remained with sinus rhythm and normal

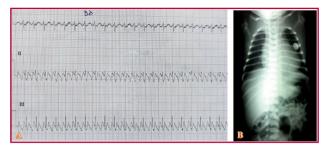


Fig. 2. A. ECG shows atrial flutter with a 2:1 conduction pattern, evidencing the typical saw-tooth P-wave pattern. B. Chest teleradiography: Cardiothoracic ratio was 63%, indicating mild cardiomegaly.



Fig. 2. ECG: In sinus rhythm after the second electrical cardioversion.

ECG, and was discharged on oral propranolol therapy for 3 months.

The prognosis of AFI depends on the occurrence of congenital heart diseases and on the response to cardioversion; therefore, babies with healthy hearts have little likelihood of recurrence, and drug treatment for long periods is discouraged. However, those patients with refractory flutter and structural anomaly often receive beta-blockers, or digoxin and beta-blockers, for at least 6 months. (2-4) Our patient did not present with structural heart disease but systolic dysfunction that was overcome. Cardioversion for neonatal AFl with only 0.25-0.5 J/kg is often successful, with a success rate of about 90%; (5) our patient underwent two electrical cardioversions despite continuous amiodarone infusions to restore sinus rhythm, which proved to be safe for the baby, since up to four electrical cardioversions can be performed at 1 J/kg in refractory cases. (5) Fetuses and neonates with AFl or ectopic atrial tachycardia are more likely to be macrosomic than the general population, (6) as was the case of our patient, who was large for his gestational age (weight > p 90). Differential diagnosis should consider infectious diseases, metabolic disorders, and other common arrhythmias in this age group, such as supraventricular tachycardia.

Conflicts of interest

None declared.

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Willie Jack Blacio Vidal¹,

Saida Orellana Córdova¹, Isabel Ruilova Castillo¹ 1 Department of Neonatology. Hospital Humanitario Especializado Pablo Jaramillo Crespo, Cuenca Ecuador. Willie Blacio Vidal

E-mail: wilblavi@hotmail.com Cuenca - Ecuador

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Transcaval Transcatheter Aortic Valve Replacement

Transcatheter aortic valve replacement (TAVR) is currently the strategy of choice in high-risk or inoperable patients, (1, 2) and it is a valid alternative in intermediate-risk patients, (3, 4) particularly when it can be performed via the femoral artery (V). This access has been the most used and is currently the first choice, added to the reduction of the caliber in the devices for this route. However, there are still some cases in which it cannot be used, and alternative accesses are necessary. The transapical access is one of these alternatives, which, in addition to being more aggressive, showed worse results than the femoral route in some cases. This led to other options such as the transaortic, subclavian, and carotid routes that require surgical access, and, more recently, the percutaneous transaxillary access, and the transcaval access.

All of them have their advantages and disadvantages -as well as their detractors, and a complete summary exceeds the interest of this brief letter, which is to report our first case of percutaneous transcaval TAVR following the minimalist technique, under conscious sedation and without transesophageal echocardiography (TEE).

We describe the case of a highly symptomatic patient with severe aortic stenosis who was rejected for surgery and was indicated TAVR, since the femoral access was contraindicated due to severe peripheral vascular disease (including the occlusion of the iliac arteries and a bilateral iliofemoral bypass), in addition to severe COPD as comorbidity. Therefore, transcaval access was decided.

A left femoral arterial puncture of the bypass was performed under conscious sedation with a 6-French (Fr) introducer.

A puncture of the right femoral vein was also performed with a 6-Fr introducer and a percutaneous suture was placed with a 10-Fr Perclose device (Abbott Vascular, Abbott Park II USA); then, a super stiff guidewire together with it an 18-Fr introducer were inserted to the infrarenal inferior vena cava.

Next, simultaneous aortography and venography were performed to confirm the closest site between the vena cava and the abdominal aorta, already identified with angiotomography which, in turn, had also been ruled out due to significant calcification in that segment of the aortic wall (Figure 1).

A 20-mm loop snare was advanced through the arterial puncture, and a triaxial system –composed of a 6-Fr renal guide catheter (allowing good orientation) containing a 5.0 x 40 mm balloon for 0.035' guide– was inserted through the venous sector, with a 0.018' guidewire inside, to which the proximal flexible end had been cut and the distal end had been connected to the electrosurgical knife in cut mode.

By directing the guidewire towards the loop snare, penetration is performed by perforating the wall of the inferior vena cava (IVC) and abdominal aorta (AA); the guide is snared and progressed towards the proximal thoracic aorta near the subclavian artery. The balloon is advanced and then exchanged for a 0.035' super stiff guidewire, the path is predilated and an 18-Fr introducer is advanced from the IVC to the AA, through which the aortic valve is implanted following the usual technique. Once the implantation is completed –leaving a back-up guide to prevent inadvertent migration, the path is closed with a 10 mm occluder device for muscular ventricular septal defect (VSD). Once the closure is confirmed, there is usually a residual flow (aortocaval fistula for a few minutes); subsequently, the whole system is removed and heparinization is reversed (Figure 2).

The venous access is also closed, either with percutaneous suture -as in our case, or with a Z-stitch using polypropylene (Prolene \mathbb{R}) 0 in the subcutaneous tissue.

The maneuvers and rescue elements that should always be available are the aortic balloons and stent graft of adequate diameter in case of significant bleeding, which occurs in less than 5% of cases.

When the procedure was completed, the patient was monitored in the coronary care unit and discharged the next morning.

Although the minimalist transfemoral approach seems to be the global trend, the debate continues about which access to use when the transfemoral route is not possible. While the transcaval access looks intimidating, it is a non-aggressive approach with quite predictable outcomes. One has to be prepared for complications that –while uncommon– could be life-threatening.

Light bleeding -in general due to pressure difference mechanisms-, if it is well managed, avoids blood collection and allows spontaneous drainage towards the vena cava; in fact, in some cases (such as ours), it happens in the first few minutes through the body of the occluder device. However, we must be ready to resolve major bleedings (BARC type 4) (6) as if it were an aortic perforation, for which the necessary elements should be available to allow for a quick and effective resolution.

As described in some international series, transcaval access was possible in our patient, with excellent initial outcomes.



Fig. 1. A. CT angiography; left iliofemoral and right femorofemoral bypass, and severe bilateral iliac calcification. B-C. Distance between the aorta and the vena cava in sites without calcium and suitable for cavo-aortic puncture marked with arrows by tomography and (D) angiography.

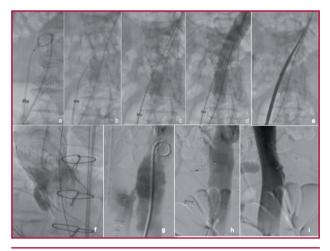


Fig. 2. A. Loop snare in the abdominal aorta with telescoping system, including an 18-Fr introducer, 6-Fr catheter, 5.0 x 20 balloon, and a 0.018" guidewire in the inferior vena cava. B. Perforation with the guidewire in the wall of the vena cava and the aorta penetrating the abdominal aorta. C. Over-the-wire balloon crossing. D. Follow-up aortography. E. Transcaval 18 Fr introducer to the abdominal aorta. F. Final outcome: implantation of CoreValve Evolut R[™] G. Placement of the occluder device with a protective 0.018" guidewire in parallel. H. Final outcome in the aortography. I. Final cavography.

Conflicts of interest

None declared.

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

Oscar A. Mendiz, Carlos M. Fava, Paul Gamboa, León Valdivieso, Gustavo Lev, Gaspar Caponi

> ICyCC - Instituto de Cardiología y Cirugía Cardiovascular Hospital Universitario Fundación Favaloro. Department of Interventional Cardiology. Oscar Mendiz omendiz@ffavaloro.org

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