ORIGINAL ARTICLE

Aortic Valve Sparing Surgery as Alternative in Aortic Root Disease. Long-term Outcomes

Cirugía de preservación valvular como alternativa en enfermedad de la raíz aórtica. Resultados alejados

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ABSTRACT

Background: Since 1968, ascending aorta replacement with a valved conduit has been the standard practice for aortic root aneurysm. By the end of the 20th century, aortic valve sparing operation emerged and evolved as an alternative to aortic valve replacement.
Objective: The aim of this study was to report our experience with aortic valve sparing technique and its long -term outcomes.
Methods: A total of 116 consecutive cases with criteria of repairability operated on between 2005 and 2019 were analyzed. Preoperative transesophageal echocardiography (TEE) and computed tomography angiography (CTA) were used in combination to determine the aortic phenotype based on a previous anatomical and functional classification. Perioperative control was performed and conversion to aortic valve replacement was left to the discretion of the attending surgeon. Intraoperative variables, in-hospital morbidity and mortality, freedom from significant aortic regurgitation (AR) and reoperation in the clinical and echocardiographic follow-up were reported.
Results: Mean age was 56±15.6 years and 73% were men; 59% were asymptomatic, and the reason for the intervention was the aortic diameter (52±11.7 mm) or progression of AR. After the procedure, 4% of the cases presented mild or trivial AR and 2 patients required conversion to aortic valve replacement (1.7%). In hospital mortality was 0.9%. Actuarial survival was 88% at 10 years, and 79% were free from significant (moderate/severe) AR. Five cases underwent reoperation after a mean interval of 9.1 years and freedom from reoperation at 10 years was 90%. There were no major thromboembolic or bleeding events.
Conclusion: Aortic valve sparing technique in the setting of aortic root disease is a feasible and safe option, and stable over time.

Keywords: Aortic valve - Aneurysmal disease - Valve sparing procedure

RESUMEN

Introducción: Desde 1968, la enfermedad aneurismática de la raíz aórtica ha sido tratada mediante el remplazo con tubo valvulado. En las últimas décadas la cirugía de preservación valvular surgió y evolucionó como una opción al remplazo protésico.
Objetivo: Reportar la experiencia institucional en la técnica de preservación valvular y sus resultados a largo plazo.
Material y métodos: Revisión de 116 casos consecutivos con criterios de reparabilidad, intervenidos entre 2005 y 2019. Previo ecocardiograma transesofágico (ETE) y angiotomografía (AngioTc), se procedió quirúrgicamente acorde a la clasificación anatomofuncional, con la combinación de técnicas. Se realizó control intraoperatorio y conversión a remplazo según el criterio del cirujano interviniente. Se reportan las variables intraoperatorias, la morbimortalidad intrahospitalaria y la mortalidad, la libertad de insuficiencia valvular significativa y la reoperación en el seguimiento clínico y ecocardiográfico.
Resultados: La edad media era 56 ± 15,6 años, varones 73%, 59% asintomáticos, intervenidos por diámetro aórtico (52 ± 11,7 mm) o progresión de valvulopatía. En el posprocedimiento, 4% de los casos resultó con insuficiencia leve o nula y 2 conversiones (1,7%); mortalidad hospitalaria 0,9%. A 10 años de seguimiento, sobrevida actuarial del 88% y libertad de insuficiencia significativa (moderada/grave) 79%. Se reintervinieron 5 casos, a un intervalo promedio de 9,1 años y libertad de reoperación de 90% a 10 años. No se registraron eventos tromboembólicos ni hemorrágicos mayores.
Conclusión: las técnicas de preservación valvular aórtica, en contexto de enfermedad de la raíz, resultan una opción factible, segura y estable en el tiempo.

Palabras clave: Válvula aórtica - Aneurisma - Preservación valvular

INTRODUCTION

Since the publications by Bentall in 1968, replacement of the ascending aorta and aortic valve by insertion of a biological or mechanical valved conduit has been the standard treatment for aortic root aneurysm, independently of the degree of valvular disease. (1) This technique constitutes a valid, feasible and reproducible option in cases of aortic valve stenosis with aortic root or proximal aorta involvement. However, in the case of pure aortic valve regurgitation, the pres-

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ence of a dysfunctional but structurally normal valve casts doubt on the need for valve replacement and its implications, either the anticoagulation required for mechanical prostheses, structural deterioration and subclinical thrombosis of bioprostheses, or the risk of endocarditis for both types of prostheses.

In the eighties, Yacoub (2) introduced the concept of root remodeling, and 10 years later David and Feindel published their series using the reimplantation technique. (3) Since then, hundreds of publications have witnessed the progress of the technique, its pathophysiological classification, the optimal anatomical conditions for its implementation, patient selection and the methods for evaluation before and after the procedure, with morbidity and mortality rates that are comparable and even better than those of conventional replacement. Similar to mitral valve repair, of proven advantages, the implementation and expansion of aortic valve repair has certain limitations due to technical requirements and the considerable risk of failure, in addition to scarce information on feasibility and results in our environment.

In 2005, our institution initiated a valve-sparing program that has evolved to become the first option in patients with aneurysmal disease, in the absence of valve degeneration or stenosis. The aim of this presentation is to review the pathophysiological classification and criteria for patient selection and report the short- and long-term outcomes in terms of recurrence of aortic regurgitation (AR) and reoperation, in order to promote its use, which is widely recommended but scarcely implemented. (4, 5)

METHODS

Study population

Between January 2005 and December 2019, 712 patients were referred to our department with diagnosis of ascending aorta aneurysmal disease with surgical indication based on clinical guidelines. (6, 7) Patients with significant aortic stenosis, acute dissections, active endocarditis, reoperation or with echocardiographic criteria of non-repairability (8) were excluded from the study; finally, 116 patients were consecutively included in a valve repair program, with annual follow-up according to the protocol. All the patients were informed about the possibility of aortic valve repair and gave their consent for the procedure.

Preoperative clinical data

Before surgery, all patients underwent transthoracic echocardiography, transesophageal echocardiography (TEE) and multislice computed tomography scan of the thoracic aorta. Echocardiographic studies were performed with a Philips iE33 ultrasound machine using a S5-1MHz transducer and X7-2t MHz multiplanar probe or a Philips EpiQ 7 ultrasound machine with a xMatrix 2D/3D transducer and 3D 7 MHz transesophageal probe.

The presence and severity of AR, ventricular dimensions, systolic function and aortic root dimensions were evaluated by transthoracic echocardiography, following the recommendations of the American and European Cardiology Association societies (absence, mild, moderate or severe regurgitation). (9) Transesophageal images were obtained in short axis and long axis views rotating the probe between 0 to 180 degrees. The aortic valve assessment included the number of aortic cusps and for bicuspid aortic valves, the presence or absence of raphe and symmetry. Cusp motion was reported as normal, excessive or restrictive. Aortic valve prolapse was defined as diastolic eversion or bulging of the free edge towards the left ventricular outflow tract below the annular plane. The presence and type of fibrosis or calcification was also determined. (8)

The direction of the regurgitant jet was evaluated with color-Doppler echocardiography. In the sagittal plane, aortic annulus, sinus of Valsalva, sinotubular junction (STJ), and ascending aorta (in 2D and 3D mode, with multiplanar reconstruction) diameters were measured, thereby determining the phenotype of the aneurysm. (9).

Computed tomography angiography (CTA) was performed with ECG-gating and three phase image acquisition with an arterial phase at 75% of the cardiac phase. Maximal aortic annulus, sinus of Valsalva, STJ and ascending aorta diameters were measured perpendicular to the aortic long axis. Valvular configuration, annular geometry, supra-aortic vessel arrangement and presence of coronary artery disease were also evaluated. Coronary angiography was performed in case of non-conclusive findings. The anatomical and functional classification of aortic phenotype modified by El Khoury (Figure 1) was used to guide the selection of the surgical technique. (10)

Surgical procedure

All the interventions were performed via median sternotomy and with cardiopulmonary bypass (CPB) by direct cannulation of the aortic arch or right axillary artery, depending on the distal extension of the aneurysm. Intermittent blood cardioplegia and pulmonary venting were used. A high transverse aortotomy was performed to inspect the aortic valve, the cusp number and arrangement, the presence of fenestrations, the location and extension of the raphe, the incidence of fibrosis or calcification, and the geometric height of the cusps to determine the feasibility of repair, as well as the aortic annulus and sinus of Valsalva diameter and the characteristics of the aortic wall, regardless of its diameter.

As previously mentioned, the technique was selected according to the anatomical and functional classification. Cases with dilation above the STJ (subtype Ia) were treated with aorto-aortic graft and reimplantation or remodeling was used in subtypes Ib and Ic. Initially, the decision was left to the discretion of the surgeon, but nowadays it is based on the aortic annulus diameter (remodeling if the annulus diameter is ≤25 mm, reimplantation if it is >25 mm), determined by intraoperative echocardiography or sizing.

Exceptionally, a restrictive annulus was treated with annuloplasty using PTFE 2.0 or Teflon band (Figure 1). Type II lesions (cusp prolapse) diagnosed before surgery or during the procedure were treated with plication or resection of the free margin to adjust the geometric size by 8-10 mm. Restrictive valve disease, characteristic of bicuspid aortic valves, required raphe resection and primary closure or plication with separate stitches of polypropylene 6.0 suture, depending on its extension and insertion at the level of the fused commissure.

After repair, intraoperative echocardiography was performed with Philips iE33 and Sonosite Turbo ultrasound machines using a transesophageal multiplanar probe with a frequency of 8-3 MHz. Presence, degree and cause of residual regurgitation were evaluated, paying special attention

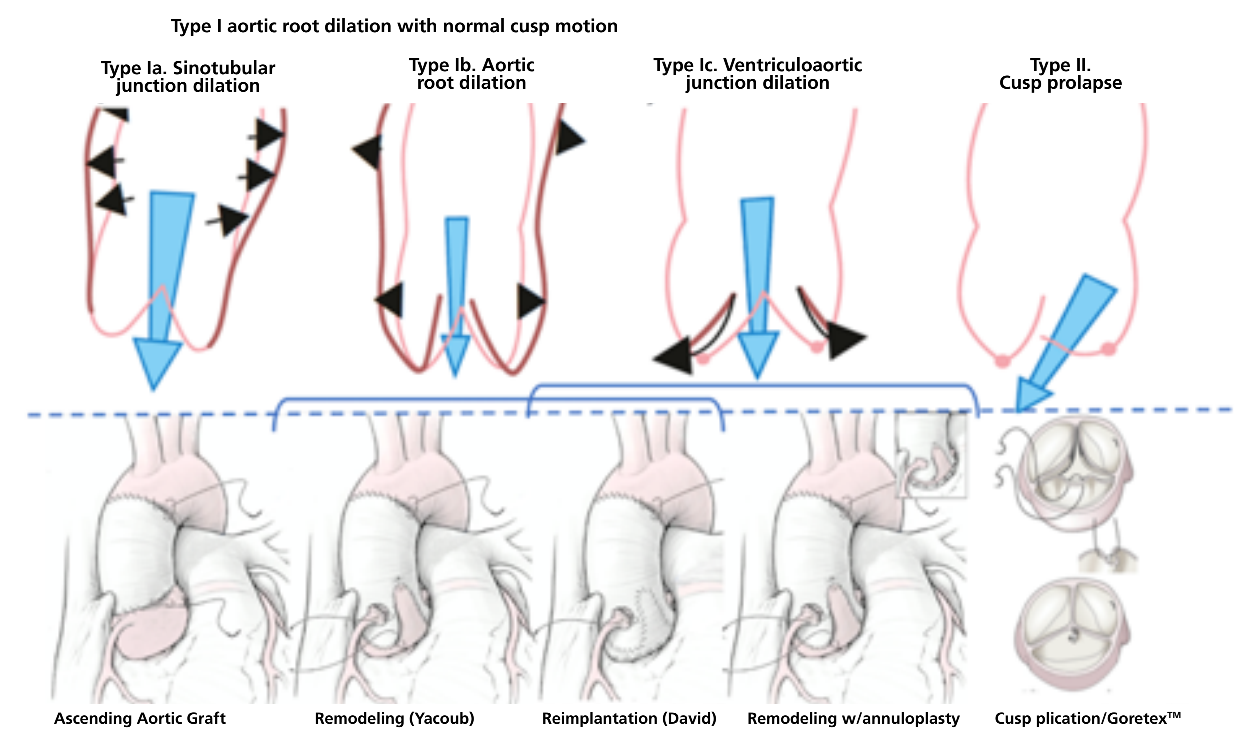

Fig. 1. Top: Functional classification of aortic regurgitation revised by El Khoury et al. (10) (excluding type Ic, perforation and type III, restrictive). Bottom: Surgical technique used. Lesions type I and II may coexist, resulting in complementary surgical techniques

to the surface and coaptation height, the presence of residual prolapse, direction of the regurgitant jet, aortic area and transaortic gradient. Conversion to aortic valve replacement was decided by the attending physician based on the echocardiographic findings, age, clinical status and comorbidities.

Follow-up

Perioperative morbidity and mortality were determined following conventional definitions (Appendix 1). All patients were evaluated with echocardiography before discharge and were followed up at the valvular heart disease clinic. Clinical and ecocardiographic assessment were repeated at 3, 6 and 12 months, and CTA was performed once a year. Transesophageal echocardiography was indicated in case of suspected endocarditis, increased aortic gradient or progression of AR. In the evaluation of survival curves and recurrence of significant regurgitation, valve morphology (bicuspid or tricuspid) was considered, associated with different results in previous publications.

Statistical analysis

Quantitative variables were expressed as mean ± standard deviation, or median and interquartile range, according to their distribution, Qualitative variables were presented as percentage. Event-free survival curves were estimated using the Kaplan- Meier method. The differences in survival between groups were analyzed with the log-rank test. Univariate and multivariate Cox proportional hazard analyses were performed to investigate the significant predictors of late mortality. The clinical variables listed in Table 1 were used for univariate analysis, and those with $p < 0.2$ were included in the multivariate model.

Ethical considerations

The study was conducted following national and international ethical standards for research on human subjects (Declaration of Helsinki, and others). The investigators implemented measures to protect the confidentiality of all the information according to the Argentine personal data protection law 25,326. An identifying code number was assigned to patients, and their personal data were kept anonymous.

RESULTS

Median age was 56±15.6 years (range 18-78), 73% were men, and body surface area was 1.99±0.2 m^2. Baseline population characteristics are shown in Table 1. The main indication for the intervention was aortic diameter indexed to body surface area or its progressive enlargement or family history. Diagnosis of Marfan or Loeys Dietz syndromes was made in only 10.3% of the cases.

Surgical procedure and results

According to the aortic phenotype, 17 cases (15%) underwent aorto-aortic replacement (subtype Ia), 16 cases (14%) underwent remodeling and the remaining 83 cases (71%) underwent reimplantation (subtypes Ib and Ic).

Two patients undergoing remodeling (12.5%) also required external annuloplasty. The surgeon decided to plicate the aorto-ventricular junction, either by reimplantation or external annuloplasty, based on previous measurements (mean aortic annulus diameter

Table 1. Global preoperative variables

Risk factors	% (n)
Hypertension	61.8 (71)
Dyslipidemia	30.7 (35)
Smoking habits	39.6 (46)
Diabetes	1.7 (2)
Family history	22.4 (26)
Personal history (N = 116)	**% (n)**
Previous stroke	2.5 (3)
Moderate/severe pulmonary disease	6.5 (8)
Previous kidney failre	6.8 (8)
Previous myocardial infarction	0.8 (1)
Previous PCI	3.4 (4)
Significant coronary artery disease	9.4 (11)
Predominant clinical condition	**% (n)**
Asymptomatic	59 (66)
Progressive dyspnea	30 (35)
Unstable angina	6 (7)
Heart failure	0.8 (1)
Syncope	3.4 (4)
Echocardipgraphy	**% (n)**
LV diastolic dimension. (mm) (mean/SD)	55 ± 9.1
LV systolic dimension. (mm) (mean/SD)	34 ± 9.1
Moderate/severe ventricular function % (n)	9.3 (35)
Bicuspid aortic valve % (n)	21.6 (35)
Preoperative aortic regurgitation %	75.8
- Grade 0 % (n)	6 (7)
- Grade 1% (n)	19.8 (23)
- Grado 2 or greater % (n)	74.2 (86)
Fibrosis - calcification grade 2/3** % (n)	5.1 (6)
Cusp prolapse % (n)	18.1 (21)
Computed tomography scan	**% (n)**
Aortic annulus diameter, (mm)	26 ± 4.5
Valsalva sinuses diameter, (mm)	49.5 ± 7.8
STJ diameter, (mm)	52 ± 11.7
Aortic diameter (mm)	42 ± 8

PCI: percutaneous coronary intervention. LV: Left Ventricle
STJ: Sinotubular Junction

26±3.3 mm for all the population; 23±3.6 mm for the remodeling group vs. 27±4. mm for the reimplantation group). The association of type 2 AR (prolapse on echocardiography or on direct inspection) was 55%, with no differences between the groups. Direct plication was the most used technique, particularly in the reimplantation group.

Other techniques were modified throughout the series, such as early discontinuation of resuspension with subcommisural stitches or Gore-Tex® suture on the free margins. Once CPB was discontinued, TEE identified 94% of patients without significant AR and 7 patients (6%) with moderate to severe AR, with a conversion rate to aortic valve replacement of 1.7% (2 cases). In the remaining 5 cases (3%), residual regurgitation occurred within the first 5 years of the program and was not intervened considering patients' age, prolonged CPB time and associated comorbidities. The intraoperative data and results are summarized in Table 2.

Periprocedural morbidity and mortality

The incidence of periprocedural complications described in Table 3 was low.

Clinical and echocardiographic follow-up

Median follow-up was 4 years (1.9-8.8), and 3 patients (2.6%) were lost to follow-up. Eight patients died, 2 due to cardiovascular causes: one sudden death and one valvular dysfunction. Actuarial survival at 10 years was 88%, without differences in the aortic phenotypes (Figure 2A).

Five patients required elective reoperations: 3 cases (2.6%) due to endocarditis 4 and 6 years after surgery, 1 case due to progression of the residual AR 4.9 years after surgery and 1 patient due to aortic stenosis 10.6 years later. No major complications or deaths were reported after reoperation. A sixth patient with indication of reoperation due to residual stenosis refused the new surgery and represents one death due to cardiovascular causes. Freedom from reintervention was 91% at 10 years (Figure 2B).

Recurrence or progression to significant AR detected by echocardiography occurred in 12 patients (10.4%) at an average of 5.8 years since the intervention (Figure 2C). Freedom from significant AR at 10 years was 79% (Figure 2D). Multivariate Cox regression analysis identified eccentric jet as an independent predictor of long-term progression (HR 17.6; 95% CI, 3.7-84.1; $p < 0.0001$).

Left ventricular ejection fraction (LVEF) was >50% in 87% of patients, with improvement of left ventricular diameters (diastolic dimension 54±9.1 mm before surgery and 49±6.5 mm after surgery; systolic dimension 34±9 mm before surgery and 30±5.8 mm after surgery, $p \leq 0.01$), and stable residual gradients (8±6.2 mm Hg) and peak aortic jet velocity (1.4±0.5 m/sec).

Ninety-two percent of surviving patients (99/108) were in FC I, independently of the degree of residual AR diagnosed by imaging studies. Four patients were treated with anticoagulants during follow-up due to aortic valve replacement with mechanical prosthesis, but no bleeding events or thromboembolic events associated with the treatment were reported.

DISCUSSION

Although aortic valve-sparing techniques have demonstrated excellent long-term results and stability in many publications (11-15), its actual implementation is still low and limited to high-volume centers with experience in heart valve surgery. Aortic valve-sparing procedures account for 19% of interventions on the thoracic aorta according to the American Society of Thoracic Surgeons registry (5) and represent 7700

Table 2. Global intraoperative variables and by surgical technique

Variable	Global N = 116 % (n)	Aortic graft N = 17 % (n)	Remodeling N = 16 % (n)	Reimplantation N = 83 % (n)
- Leaflet plication	28.4 (33)	11.8 (2)	25 (4)	32.5 (27)
- Leaflet resection	8.6 (10)	11.8 (2)	25 (4)	4.8 (4)
- Subcommisural stitches	18.9 (22)	52.9 (9)	25 (4)	10.7 (9)
- PTFE suture	3.4 (4)	5.9 (1)	0	3.6 (3)
Graft diameter (mm) (mode/range)	30 (24-34)	28 (26-34)	38 (26-30)	30 (24-30)
Associated CABGS	10.3 (12)	29.4 (5)	0	8.4 (7)
Aortic cross-clamp time, (min) (mean/SD)	153 ± 48	71 ± 22	142 ± 44	164 ± 34
CPB time (min) (mean/SD)	178 ± 52	87 ± 31	162 ± 47	183 ± 38
External annuloplasty	2.5 (3)	5.9 (1)	12.5 (2)	0
Without residual regurgitation	45.7 (53)	35.2 (6)	37.5 (6)	49.4 (41)
Trivial-mild AR	48.3 (56)	58.8 (10)	56.2 (9)	44.5 (37)
Moderate/severe AR	6 (7)	5.8 (1)	6.2 (1)	6 (5)
Conversion/replacement	1.7 (2)	0	6 (1)	1.2 (1)

AR: aortic regurgitation; CABS: coronary artery bypass graft surgery; CBP: cardiopulmonary bypass; SD: standard deviation

Table 3. Global perioperative complications and by surgical technique

Variable	Global N = 116 % (n)	Aortic graft N = 17 % (n)	Remodeling N = 16 % (n)	Reimplantation N = 83 % (n)
Moderate bleeding	20.7 (24)	17.6 (3)	25 (4)	20.4 (17)
Reoperation for bleeding	4.3 (5)	0	0	6.2 (5)
Atrial fibrillation	22.4 (26)	17.6 (3)	37.5 (6)	20.4 (17)
Inotropic agents > 24 h	24.1 (28)	23.5 (4)	6.25 (1)	27.7 (23)
Prolonged MV	3.4 (4)	5.9 (1)	6.25 (1)	2.4 (2)
Permanent pacemaker	2.6 (3)	0	0	3.6 (3)
Kidney failure	6.03(7)	11.7 (2)	0	6.02 (5)
Dialysis	0.9 (1)	0	0	1.2 (1)
Stroke with sequelae	0.9 (1)	0	0	1.2 (1)
Mortality	**0.9 (1)**	**0**	**0**	**1.2 (1)**
Length of hospital stay (days) (mean/SD - range)	5 ± 5.8 (4-50)	5 ± 3.8 (4-19)	5 ± 6.6 (4-15)	5.5 ± 2.8 (5-50)

MV:mechanical ventilation

cases over a 5-year period in the AVIATOR registry, with participation of 55 European centers. The advantages of this technique include low rate of complications, especially anticoagulation and thromboembolic events, and an optimal hemodynamic profile and stability over time. Aortic valve-sparing operation is sometimes criticized due to its technical difficulty, learning curve and doubtful durability, apart from the proven efficiency and standardization of the Bentall procedure.

Several groups have compared valve-sparing techniques with the insertion of the traditional biological or mechanical valved conduit in terms of morbidity, mortality and freedom from reintervention, with different results. (16-18) Although there are no prospective randomized studies comparing strategies, a recent meta-analysis by Elbatarny (with 6218 patients in 26 publications) demonstrates considerable advantage with the valve-sparing technique, represented by reduction of mortality, bleeding and thromboembolic events of 32%, 71% and 64%, respectively, after a follow-up of 5.8±3.0 years. (19)

Our group is convinced of the advantages of the technique and has established a protocol of preoperative echocardiography studies to evaluate the success of the procedure from the analysis and anatomo-functional assessment of its images. (7, 20-23). As in the case of mitral valve repair, restrictive type III phenotypes have poor long-term outcomes (7, 20); the effective cusp height ≤16 mm in tricuspid aortic valves and ≤19 mm in bicuspid aortic valves is associated with suboptimal results. (23) Aortic valve repair with pericardial patch or synthetic material, except for minimal fenestrations, has high rate of early recurrence, particularly in patients with bicuspid aortic valve, and is thus not recommended in this type of lesions. (24, 25)

In addition, the presence of significant fibrosis or calcification, especially of the raphe in bicuspid aortic valves, is a determining factor for the success of valve repair and should be reported in the preopera-

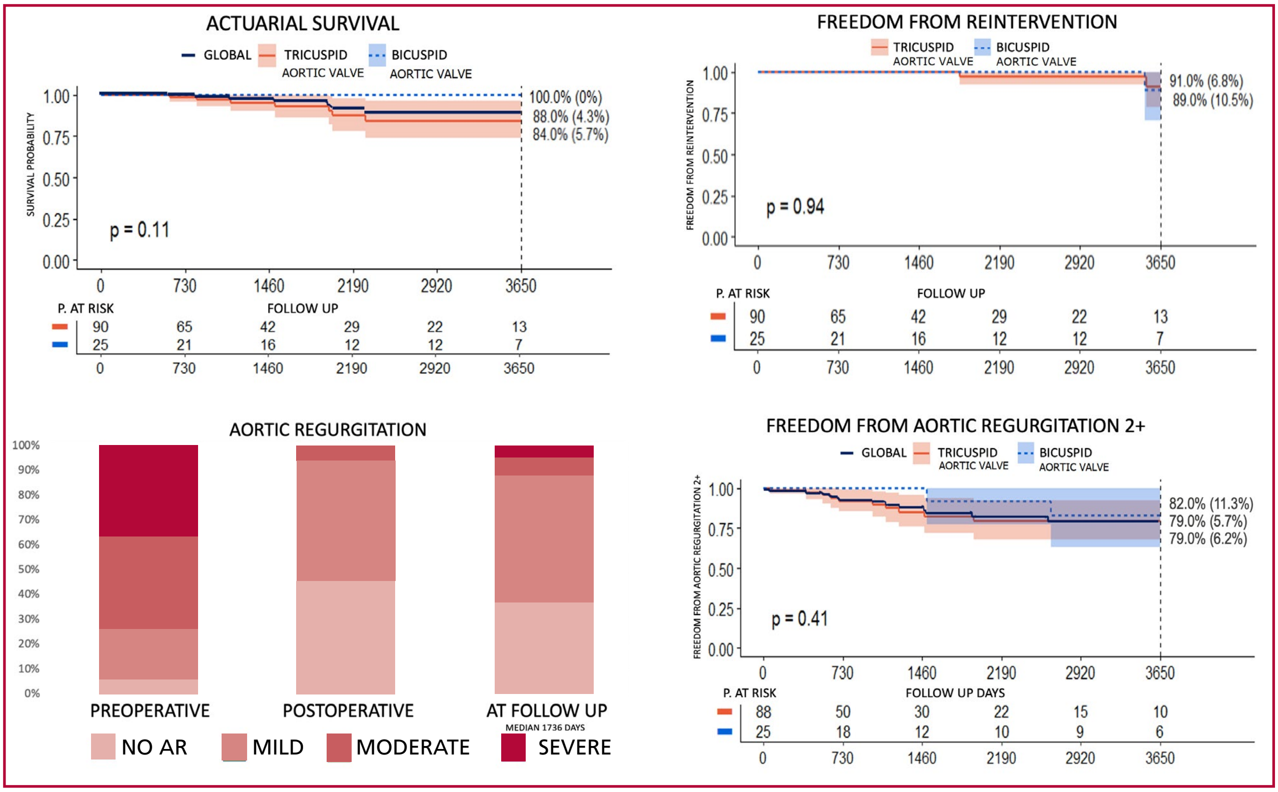

Fig. 1. A. Actuarial survival (global and by aortic phenotype). **B.** Freedom from reintervention in the aortic valve (global and by aortic phenotype) **C.** Degree of aortic regurgitation (AR) before surgery, after surgery and at median follow-up. **D.** Freedom from significant AR (global and by aortic phenotype).

tive evaluation. (26)

The correlation between the echocardiographic report and the intraoperative finding was relatively high, with differences in the detection of prolapse that did not affect the final result. The definition of the aortic annulus diameter by echocardiography or CT scan is essential to decide the surgical technique. In non-treated aortic annuli with a diameter >25 mm, the recurrence of AR is high; therefore, external annuloplasty or reimplantation should be performed to achieve stabilization of the aortic annulus and justified the use of this technique in most of our cases. (27-30)

Despite our study was not designed to compare the outcomes in relation with the aortic phenotype, patients with aorto-aortic graft had lower rate of significant AR recurrence. Central jets (characteristic of this phenotype) are associated with more stable repair during follow-up in contrast to eccentric jets, which we identified as predictors of AR progression, regardless of the degree of regurgitation. Lansac et al. suggested an algorithm for the management of more than trivial residual eccentric AR due to previous prolapse with suboptimal treatment, or restrictive repair. (23) This situation and its proper interpretation represent the greatest challenge and is, besides the technical skill required, the practical representation of the learning curve. (31) The association of type I and type II lesions and their complex correction, had no impact on the progression of AR or on the reoperation rate, as was previously reported. (32).

The morbidity and mortality of the series was excellent, even lower than those of large series published and considered in two meta-analyses in the last decade. (16, 19, 33) The reduction of ventricular dimensions which contributed to preserve LVEF correlates with the FC observed and the long-term survival reported.

There is a clear limitation in the definition of durability or stability of valve repair; is it just an echocardiographic observation or the actual indication for intervention? Defined as echocardiographic progression, freedom from significant AR at 10 years ranges from 80% to 90%, regardless of the type of procedure and valvular phenotype. David and El Khoury, pioneers of the reimplantation technique, reported 89.4% and 92% freedom from significant AR, respectively, at 10 years (34, 15). For Yacoub and Schafers, supporters of remodeling, freedom from significant AR was 89% and 80%, respectively, both series with low use of annuloplasty. (35, 14) In our setting, Escarain reported similar values, 84% at 8 years. (36). This recurrence is well tolerated in patients with significant previous AR and dilated ventricle, which condition the indication for reintervention. Therefore, if durability is represented by the reoperation rate, the results of our series are encouraging. Freedom from intervention at 10 years rarely falls below 90%, except for bicuspid aortic valve in inadequately selected patients (restrictive leaflets, asymmetric configuration, annuloaortic ectasia). (37)

The experience brings us closer to concepts associated with the undisputed success of mitral repair: a. adequate assessment of imaging studies; b. anatomical and functional classification: there is a technique for each defect; c. identification of failure predictors; d. surgeon's experience; e. intolerance to residual regurgitation; and f. volume-dependent learning curve.

CONCLUSION

Aortic valve sparing procedures are safe and durable, with optimal results in terms of quality of life, survival and need for reintervention, and should be considered as an option in patients with aortic root aneurysm, irrespective of the degree of associated regurgitation, especially in those who reject anticoagulation treatment or have contraindications for its use. The identification of the functional anatomy and correct aortic phenotype can classify not only patients who are candidates for valve preservation, but also those who have shown extended benefits over time. Correct patient selection and implementation of the technique in high-volume centers are the key to long-term success.

Conflicts of interest

None declared.

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

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