ORIGINAL ARTICLE

Aortic Annulus Enlargement vs. Conventional Surgery in Patients with Small Aortic Annulus Undergoing Aortic Valve Replacement

Ampliación del anillo aórtico vs. cirugía convencional en pacientes con anillo pequeño sometidos a reemplazo valvular aórtico

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ABSTRACT

Background: The goal of aortic valve replacement for severe stenosis is to relieve symptoms and prevent the mortality associated with the disease. Appropriate prosthetic valve size must be selected for each patient according to body surface area to avoid patient-prosthesis mismatch.
Objective: The aim of this study was to evaluate transvalvular gradient reduction at one-year follow-up in patients with small aortic annulus undergoing valve replacement with annular enlargement vs. conventional replacement surgery.
Methods: A retrospective cohort study was performed including patients with small aortic annulus undergoing valve replacement from January 2011 to December 2015. Two groups were selected: Group AAE consisting of patients in whom aortic annular enlargement was necessary and Group RVA19 involving patients in whom a #19 mm prosthetic valve was conventionally implanted.
Results: Postoperative gradients (within the first 3 months and at one year) were significantly lower in the group with aortic annular enlargement. Median cardiopulmonary bypass time increased 14 minutes in Group AAE. Bioprostheses were used in most cases. There was no statistically significant difference in mortality between the groups.
Conclusions: Aortic annular enlargement improves postoperative, short-term and at one year follow-up transvalvular gradients.

Key words: Aortic Valve Replacement - Cardiac Surgery - Small Aortic Root - Patient-prosthesis Mismatch

RESUMEN

Introducción: El reemplazo valvular aórtico por estenosis grave busca el alivio sintomático y evitar la mortalidad de la enfermedad. Se debe seleccionar el tamaño de prótesis valvular adecuado para cada paciente según su superficie corporal, evitando la disociación paciente-prótesis.
Objetivo: Evaluar la reducción de los gradientes transvalvulares al año de seguimiento en pacientes con anillo aórtico pequeño sometidos a reemplazo valvular con técnica de ampliación del anillo versus reemplazo convencional.
Material y métodos: Estudio de cohorte retrospectivo que incluyó pacientes con anillo aórtico pequeño sometidos a reemplazo valvular desde enero de 2011 hasta diciembre de 2015. Se conformaron dos grupos: Grupo AA, pacientes en los que fue necesaria la ampliación del anillo y Grupo RVA19, pacientes en los que se implantó una prótesis valvular #19 mm en forma convencional.
Resultados: Los gradientes transvalvulares posoperatorios (dentro de los 3 meses y al año) fueron significativamente menores en el grupo ampliación del anillo. Se registró un aumento de 14 minutos en la mediana del tiempo de circulación extracorpórea en el Grupo AA. Se utilizaron prótesis biológicas en la mayoría de los casos. No se observó diferencia estadísticamente significativa en la mortalidad entre los grupos.
Conclusión: La ampliación del anillo mejora los gradientes transvalvulares en el posoperatorio, a corto plazo y al año de seguimiento.

Palabras clave: Reemplazo valvular aórtico - Cirugía cardíaca - Estenosis valvular aórtica - Mismatch paciente-prótesis

Abbreviations

AAE	Aortic annulus enlargement	**CABG**	Coronary artery bypass grafting
EOA	Effective orifice area	**PPM**	Patient-prosthesis mismatch
CPB	Cardiopulmonary bypass	**AVR**	Aortic valve replacement

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INTRODUCTION

The purpose of aortic valve replacement (AVR) due to severe aortic valve stenosis is to relieve symptoms and avoid the mortality associated to natural disease progression by allowing remodeling and regression of the left ventricular mass subjected to pressure overload. To achieve this requires adequate prosthesis size selection according to patient body surface area to avoid patient-prosthesis mismatch (PPM). This phenomenon is present when the effective orifice area (EOA) of the implanted valve is too small for the patient body surface area. The concept of PPM was first described by Rahimtoola (1) in 1978, and later Pibarot et al. (2) defined it as indexed EOA under 0.85 cm^2/m^2. The annulus and aortic root anatomy added to the characteristics of the different valve prostheses available in the market, determine that it is not always possible to avoid PPM. The presence of PPM may condition lack of regression of left ventricular mass, absence of functional class improvement, greater incidence of cardiovascular events and lower survival. (2). Patient-prosthesis mismatch is an independent factor of late mortality associated with 60% increased risk of heart failure. (3) Therefore, different techniques have been developed to implant an appropriate valve according to the patient's body surface area. Homografts, stentless valves and aortic annulus enlargement (AAE) are the different techniques available. Aortic annulus enlargement has been shown to be a reproducible and safe technique, and in addition it is not an independent factor of AVR operative mortality.

The present study evaluated the usefulness of AAE. Patients with small aortic annulus undergoing AVR with AAE technique were compared with conventional surgery using a #19 prosthesis. The primary endpoint was to assess peak and mean transvalvular gradients in both groups at one-year follow-up. The secondary endpoint was to evaluate postoperative functional class, rehospitalizations for heart failure and mortality.

METHODS

A retrospective cohort study was performed including patients with small aortic annulus undergoing AVR with annular enlargement or conventional implantation of a #19 prosthesis. The inclusion period was from January 2011 to January 2015, and each patient was followed-up for 12 months. Data were collected from the institutional single electronic medical record and, in case of missing data, from telephone calls to the patient.

Small aortic annulus was defined as the one that after removal of the pathologic valve and aortic annulus decalcification admitted the implantation of a #19 or smaller prosthesis.

Inclusion criteria were patients with small aortic annulus undergoing AVR, associated or not to coronary artery bypass grafting (CABG). Patients undergoing combination surgery of another valve, aortic root and/or ascending aorta replacement were excluded from the study.

Two groups of patients were selected: the first (Group AAE), where the enlargement of the aortic annulus was considered necessary (49 cases) and the second (Group AVR19), where a #19 mm aortic valve prosthesis was implanted (24 cases).

Aortic annulus enlargement criteria were based on surgeon experience and patient body surface area to avoid PPM.

The following variables were recorded: age, sex, body surface area, preoperative and postoperative functional class, mean and maximum aortic gradients and left ventricular systolic function before and after surgery. Cardiopulmonary bypass (CPB) and cross-clamping times were recorded in both groups. The 2011 EuroSCORE II was used to calculate predictive surgical risk. Median sternotomy was performed with cardiopulmonary bypass using antegrade and retrograde cold blood cardioplegia. Following cross-clamping, oblique aortotomy was performed with subsequent valve resection and aortic valve annulus decalcification. In cases of small annulus, AAE was performed, using the modified Manouguian, (4) Nicks, (5) or Nicks-Nuñez techniques (Figure 1).

Statistical analysis

Due to the retrospective nature of the study and the small number of patients with small aortic annulus, all candidates were included in the study (consecutive simple randomized sampling). Power was calculated for the observed difference between groups in the primary endpoint. The

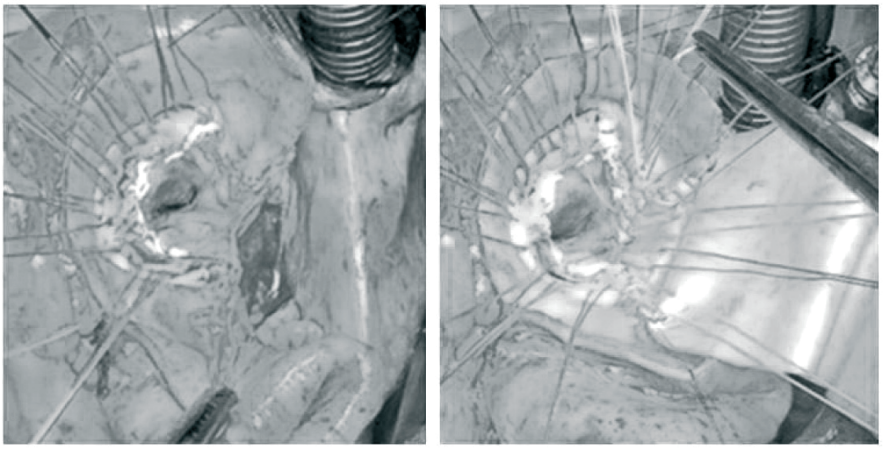


Fig. 1. Posterior annular enlargement (Modified Manouguian technique [6]). Left, incision in the non-coronary sinus towards the posterior commissure. Right, pericardial patch placement.

observed power was 69% considering a level of significance of 0.05 for a two-tailed test.

Categorical variables were expressed as percentages and continuous variables as mean and standard deviation in case of normal distribution or as median and interquartile range in case of non-normal distribution. Normality was evaluated with the Shapiro-Wilk test. Categorical variables were compared using the chi-square test or Fisher's exact test as appropriate. Continuous variables were compared using Student's t test or the Mann-Whitney test as appropriate to data distribution. A p value <0.05 was considered significant for two-tailed tests. Statistical analyses were performed using STATA 13 software package.

Ethical considerations

The study was performed following recommendations for human research and legal regulations in force. Since the study information was obtained from medical record review without reporting patient identification data, no informed consent was required from the patients (except in cases of missing data where a telephone call was made). The members of the study team implemented measures to protect data privacy and confidentiality according to legal regulations in force (Personal Data Protection Act No 25,326). The protocol was approved by the institutional Ethics Committee.

RESULTS

Preoperative patient characteristics are detailed in Table 1. There was a predominance of women in both groups. Patients in Group AAE had larger body surface area than those in Group AVR19. No significant differences were observed in the preoperative echocardiographic preoperative maximum and mean gradients, or in the left ventricular systolic function between groups.

Preoperative and postoperative data are found in Table 2. Median CPB time in Group AVR19 was 129 minutes (p_{25}=105.5 – p_{75}=152.5) and in Group AAE 143 minutes (p_{25}=126 - p_{75}=162), while median cross-clamping time was 91.5 minutes (p_{25}=72 - p_{75}=111) and 118 minutes (p_{25}=104 - p_{75}=130), respectively. These results evidence a statistically significant increase of 14 minutes in CPB time and of 26.5 minutes in cross-clamping time in Group AAE. In cases of cardiac combination surgery, 95% was associated with CABG and 5% with septal myectomy (Morrow procedure), with no difference between groups. Also, there was no statistically significant difference in in-hospital mortality between groups.

Control transthoracic echocardiograms were performed within the first 3 months and at 12 months after surgery. Maximum and mean aortic transvalvular gradients were significantly lower in Group AAE. In the 12-month echocardiograms, maximum gradients were 39.93 mmHg in Group AVR19 and 28.85 mmHg in Group AAE (p=0.048). Twelve months after surgery, poor postoperative functional class (III-IV) was found in 5.56% of Group AVR19 patients and in no case of Group AAE (p=ns). No difference in mortality was found between groups after discharge in the 12-month follow-up period. Percent rehospitalization for chronic heart failure was 5.9% in Group AVR19 and 15.9% in Group AAE (p=ns).

DISCUSSION

Small aortic annulus is defined as the annulus whose diameter does not admit implantation of at least a 21

Table 1. Preoperative characteristics of patients with small aortic annulus according to the aortic valve replacement technique used

	AVR19 n=24	AAE n=49	P
Age, years [median (IQR)]	76.5 (67 –80.5)	75 (67-78)	0.434
Body surface área, m2 [mean (SD)]	1.59±0.16	1.8±0.19)	<0.001
Female gender, %	87.5	87.8	0.975
Functional class III-IV, %	54.2	48.9	0.677
LV ejection fraction, %			0.881
Normal	92	88	
Mild impairment	4	6	
Moderate impairment	4	6	
Maximum gradient, mmHg [mean (SD)]	78.9±29.2	83.5±25.5)	0.497
Mean gradient, mmHg [mean (SD)]	47.4±20.6	51.8±18.9)	377
EuroSCORE II, median (IQR)	2.02 (1.53–2.60)	2.66 (1.59–4.20)	0.169
Isolated AVR, %	67	76	0.426
Enlargement technique, %	NA		NA
Manouguian		75.5	
Nicks		16.3	
Nicks-Nuñez		8.1	

AVR: Aortic valve replacement. AAE: Aortic annulus enlargement. IQR: Interquartile range. SD: Standard deviation LV: Left ventricular.

	AVR19 n=24	AAE n=49	P
CPB time, min [median (IQR)]	129 (105.5-152.5)	143 (126-162)	0.030
Cross-clamping time, min [median (IQR)]	91.5 (72-111)	118 (104-130)	<0.001
Type of valve, %			<0.001
Mechanical	33	14.3	
Biological	67	85.7	
Prosthesis number, %			<0.001
19	100	8.16	
21	-	69.39	
23	-	22.45	
Combined AVR, %	33	24.49	0.426
Hospital stay, days [median (IQR)]	7 (5-9)	6 (5-8)	0.497
In-hospital mortality, %	12.5	8.2	0.677
First postoperative echocardiography			
Maximum gradient, mmHg [mean (SD)]	36.3±14.9	25.3±11.5	0.001
Mean gradient, mmHg [mean (SD)]	20.8±8.6	13.9±6.5	<0.001
LV ejection fraction, %			0.172
Normal	80.95	93.62	
Mild impairment	14.29	6.38	
Moderate impairment	4.76	0	
Echocardiography at one year after surgery			
Maximum gradient, mmHg [mean (SD)]	39.92±19.03	28.85±14.46	0.048
Functional class III-IV, %	5.56	0	0.316

Table 2. Surgical results and outcome at one year follow-up according to the aortic valve replacement technique used

AVR: Aortic valve replacement. AAE: Aortic annular enlargement. CPB: Cardiopulmonary bypass. IQR: Interquartile range. SD: Standard deviation LV: Left ventricular.

mm cardiac valve prosthesis, (7-10) and is a cause of frequent PPM. It has been reported that AAE allows a significant reduction of PPM. (1) Although some years ago concerns were raised about its use due to the potential increase in perioperative risk, theoretically derived from the need of longer cross-clamping and CPB times and greater incidence of hemorrhagic complications, it is currently known that the increase in morbidity and mortality has not been demonstrated. There is disagreement regarding the impact on long-term survival of patients with PPM. Efforts to implant larger valve prostheses have been shown to be beneficial in patients with ventricular functional impairment, (11) but we believe that it would be logical to apply the same principle to all individuals undergoing AVR, maximizing the benefits of the surgical intervention with a reduction of transvalvular gradients.

Kulik et al. (8) analyzed a group of 172 patients undergoing AAE between 1989 and 2006, comparing it with 540 patients receiving ≤21 mm prostheses, and observed that a 23 mm prosthesis could be implanted in 50% of patients treated with AAE and a 21 mm prosthesis in 47% of cases. In our study, ≥21 mm prosthesis implantation was achieved in 92% of cases, and 86% of prostheses were biological. In 4 cases, (8%) a #19 prosthesis was implanted due to extremely small annulus or abundant annular calcification, precluding placement of a #21 prosthesis even with AAE.

We consider that AAE presents advantages for patients not only through the reduction of prosthetic gradients but also due to the possibility of avoiding anticoagulation. This is relevant partly because of the age of the population treated and partly because not all biological prosthesis models are available in #19 size and if they are, they present the largest postoperative gradients. We observed an increase in cross-clamping and CPB times in the study population, in accordance with available information on AAE procedures. (7, 8, 12) We consider that although the longer operative times are generated by the AAE per se, they could also be influenced by a significant percentage of combined procedures in our series. Moreover, we found that operative time prolongation did not have a statistically significant impact on in-hospital mortality, though we accept that this result could be attributed to the lack of power to detect differences due to the small number of cases, and could be clinically relevant.

Other studies have reported an incidence of reoperation for bleeding ranging between 0.9% and 5.2% in patients undergoing AAE, (8, 9) which was not observed in our cohort where there were no reinterventions. Mortality in our population was higher than that estimated by the EuroSCORE II. Although this score was used in the study, it has not been previously validated in our population of patients. Therefore, we

consider that it could potentially underestimate the operative risk, as previously described in other publications (13, 14) evaluating the performance of this score in isolated and combined procedures.

No differences were found between both groups concerning hospital stay, which differs from some studies reporting longer hospital stays in patients subjected to AAE. (8)

The enlargement technique was more frequently applied in patients with larger body surface area, as described in other clinical trials, (8, 9) and in accordance with annular enlargement criteria establishing that a larger prosthesis should be used in patients with larger body surface area to avoid mismatch.

Ninety-two percent of patients in Group AVR19 had normal preoperative ventricular function, which was reduced to 81% at one-year follow-up. In Group AAE, the percentage of patients with echocardiographically estimated normal ventricular function increased from 88% to 94%. This study cannot explain the clinical impact of this finding; we consider that it could be evaluated with a larger group of patients and longer follow-up.

Limitations

The limitations of the present study are associated to its retrospective nature, the lack of randomization of the surgical technique employed and the non-availability of the echocardiographically calculated EOA in all the included cases, leading to the use of only maximum and mean gradients.

CONCLUSIONS

Aortic annular enlargement improved postoperative and at one-year follow-up transvalvular gradients, reducing patient-prosthesis mismatch without a significant increase of complications.

Randomized studies with a larger number of patients would be necessary to evaluate mortality.

Conflicts of interest

None declared. (See authors' conflicts of interest forms on the website/Supplementary material).

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