

# Aortic valve replacement in isolated severe aortic stenosis with left ventricular dysfunction: long-term survival and ventricular recovery

*Sol ventrikül disfonksiyonunun eşlik ettiği izole ileri aort darlığında aort kapağı replasmanı:  
Uzun dönem sağkalım ve ventriküler düzelme*

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## ABSTRACT

**Objective:** The aim of this study was to assess the effects of aortic valve replacement (AVR) on the recovery of left ventricular function and the predictors for long-term survival in patients suffering from isolated severe aortic stenosis (AS) with a significant left ventricular dysfunction (LVD).

**Methods:** This retrospective study was conducted on 46 patients with isolated severe AS and LVD [left ventricular ejection fraction (LVEF)  $\leq 40\%$ ] who underwent AVR in our clinic between January 1993 and March 2006. Patients with coronary artery disease, with more than moderate aortic regurgitation ( $>2$ ), with previous valve replacement or repair, and with other valve pathologies were excluded. The mean aortic valve area was  $0.7 \pm 0.09$  cm<sup>2</sup>. The following fourteen variables were analyzed: etiology, age ( $\geq 70$  years), sex, preoperative New York Heart Association (NYHA) functional class, chronic obstructive pulmonary disease, hypertension, diabetes, peripheral arterial disease, chronic renal insufficiency, need for concomitant procedures for the ascending aorta, cardiopulmonary bypass time  $\geq 120$  min, aortic cross-clamp time  $\geq 90$  min, intraaortic balloon pump support and inotropic support. Statistical analysis for comparison of pre- and postoperative changes in clinical and functional variables was performed using Wilcoxon rank test. The predictors of early mortality after AVR were analyzed using logistic regression analysis and late survival was studied using Cox proportional regression and Kaplan Meier survival analyses.

**Results:** Operative mortality was 8.6% with four patients. As the result of univariate logistic regression analysis, preoperative NYHA functional class  $\geq 3$  was found to be predictive of early mortality. Patients with NYHA class  $\geq 3$  had 12.6 times (OR: 12.6; 95%CI: 1.2-131.3;  $p=0.035$ ) higher probability of early mortality than those with a lower NYHA class. However, multivariate logistic regression analysis demonstrated no predictor for early mortality. A positive change was observed in the LVEF in 79.3% of survivors and the mean LVEF increased from  $34.5 \pm 3.9\%$  to  $44.7 \pm 10.4\%$  ( $p<0.001$ ). There were eight (19%) late deaths. Actuarial survival was  $83.1 \pm 5.9\%$  at 5 years and  $59.6 \pm 10.9\%$  at 10 years. Cox proportional hazards regression analysis demonstrated diabetes mellitus (HR: 6.6; 95% CI: 1.19-36.9,  $p=0.031$ ) and intraaortic balloon pump use (HR: 10.7; 95% CI: 2.9-39.7,  $p<0.001$ ) as significant predictors for late mortality.

**Conclusion:** Left ventricular ejection fraction and symptoms improve after AVR in patients with isolated severe AS and LVD with an acceptable operative mortality and satisfactory long-term survival. (*Anadolu Kardiyol Derg 2009; 9: 41-6*)

**Key words:** Aortic stenosis, left ventricular dysfunction, aortic valve replacement, survival, predictive models

## ÖZET

**Amaç:** Bu çalışmada belirgin sol ventrikül disfonksiyonunun eşlik ettiği izole ileri aort darlığı hastalarında aort kapak replasmanının uzun dönem sağ kalım ve sol ventrikül fonksiyonu üzerine etkilerinin araştırılması amaçlanmıştır.

**Yöntemler:** Bu retrospektif çalışma, Ocak 1993-Mart 2006 tarihleri arasında merkezimizde aort kapağı replasmanı uygulanmış olan, sol ventrikül disfonksiyonunun [sol ventrikül ejeksiyon fraksiyonu (LVEF)  $\leq 40\%$ ] eşlik ettiği izole ileri aort darlıklı 46 hasta üzerinde yürütülmüştür. Koroner arter hastalığı, orta dereceden daha ileri ( $>2$ ) aort yetmezliği, daha önceden geçirilmiş kapak replasmanı veya onarımı ve diğer kapak patolojileri öyküleri bulunan hastalar çalışmaya dahil edilmediler. Ortalama LVEF  $34.5 \pm 3.9$  idi ve ortalama aort kapak alanı  $0.7 \pm 0.09$  cm<sup>2</sup> idi. Analize toplam 14 değişken dahil edildi: Etiyoloji, yaş ( $\geq 70$  yıl), cinsiyet, preoperatif New York Kalp Cemiyeti (NYHA) sınıfı, kronik obstrüktif akciğer hastalığı, hipertansiyon, diyabet, periferik arteriyel hastalığı, kronik böbrek yetersizliği, assandan aorta girişimleri için ihtiyaç, kardiyopulmoner bypass süresi  $\geq 120$  dk, aortik kros-klomp süresi  $\geq 90$  dk, intraaortik balon pompası desteği ve inotrop desteği. İstatistiksel analizde, ameliyat

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öncesi ve sonrası klinik ve fonksiyonel değişkenler Wilcoxon rank testi ile karşılaştırıldı. Erken hastane mortalite öngördürücüleri lojistik regresyon analiz, geç sağkalım ise Cox oransal regresyon ve Kaplan Meier sağkalım analizleri ile incelendi.

**Bulgular:** Hastane mortalitesi düşük kalp debisi sendromu nedeniyle kaybedilen dört hasta ile %8.6 idi. Tek değişkenli lojistik regresyon analizde erken mortalite öngördürücüsü olarak preoperatif  $\geq 3$  NYHA sınıfı tespit edildi. Erken mortalite olasılığı NYHA sınıfı  $\geq 3$  olan hastalarda düşük NYHA sınıfı hastalara göre 12.6 kat daha fazla idi (OR: 12.6; %95GA: 1.2-131.3;  $p=0.035$ ). Ancak, çok değişkenli lojistik regresyon analizine göre bir risk faktörü tespit edilemedi. Sağ kalan hastaların %79.3'ünde ejeksiyon fraksiyonunda olumlu yönde değişme gözlenmiş olup, ortalama LVEF %34.5 $\pm$ 3.9'dan %44.7 $\pm$ 10.4'e yükseldi ( $p<0.001$ ). Beş yıllık sağkalım oranı %83.1 $\pm$ 5.9, on yıllık sağkalım oranı ise %59.6 $\pm$ 10.9 olarak bulundu. Cox analizine göre diyabet (HR: 6.6; %95 GA: 1.19-36.9,  $p=0.031$ ) ve intraaortik balon pompası kullanımı (HR: 10.7; %95 GA: 2.9-39.7,  $p<0.001$ ) geç mortaliteyi artıran risk faktörleri olarak bulundu.

**Sonuç:** Sol ventrikül disfonksiyonunun eşlik ettiği izole ileri aort darlıklı hastalarda, aort kapak replasmanı sonrasında LVEF ve semptomların iyileşmesi beklenir. Bu hastalarda uygulanacak bu cerrahi girişim kabul edilebilir bir hastane mortalitesi ve tatmin edici bir uzun dönem sağ kalımla gerçekleştirilebilir. (*Anadolu Kardiyol Derg 2009; 9: 41-6*)

**Anahtar kelimeler:** Aort darlığı, sol ventrikül disfonksiyonu, aort kapak replasmanı, sağkalım, öngördürücü modeller

## Introduction

Severe aortic stenosis (AS) has a poor prognosis when associated with left ventricular dysfunction (LVD). The average life expectancy was reported to be less than 2 years when surgical correction was not performed (1, 2). Patients with severe AS and good left ventricular function will benefit from aortic valve replacement (AVR) with an acceptable operative mortality, an improved long-term survival and an increase in the left ventricular ejection fraction (LVEF), while those with LVD and concurrent mild or moderate AS benefit less from surgery (3-5). Because symptomatic AS has poor prognosis compared to asymptomatic AS, to optimize survival earlier AVR should be considered even in asymptomatic patients before LVD develops (4). Although AVR is the only effective treatment modality in patients with AS and LVD, perioperative risk and worse late outcomes are observed more often (6, 7).

In the literature most studies assessing the effect of AVR on ventricular function, mortality and morbidity in patients with severe AS and LVD included patients with coronary artery disease (CAD). As we aimed to evaluate the isolated effect of AVR, we excluded those patients with CAD.

The objective of this study was to assess the predictors of early and long term survival, and the effect of surgery on the recovery of left ventricular function in patients with isolated severe AS and LVD.

## Methods

### Patients

A total of 46 consecutive patients with isolated severe AS and LVD (LVEF  $\leq 40\%$ ) underwent isolated primary AVR in our clinic between January 1993 and March 2006. The study was designed in a retrospective manner and all data were collected from hospital records. This study was approved by the Research Committee of the hospital. All patients with CAD, with more than moderate aortic regurgitation ( $>2$ ), with previous valve replacement or repair and with other valve pathologies were excluded from the study. Cardiac catheterization and coronary angiography was performed in 40 patients (86.9%) preoperatively. Preoperative patient characteristics are listed in Table 1.

### Echocardiographic measurements

Complete pre-operative transthoracic echocardiographic measurements were performed by an experienced cardiologist in

all patients. Measurements of left ventricular dimensions were made from 2- dimensional echocardiographic images in the parasternal long-axis view and M-mode. Echocardiographic left ventricular volumes and LVEF were calculated by modification of Simpson's method with two apical views. Mean and peak aortic gradients were determined by Doppler measurements, and native aortic valve orifice area was calculated by the continuity equation. Left ventricular mass was calculated using Devereux-modified American Society of Echocardiography (ASE) equation considering the diastolic measurements of left

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

Age, years	55.02 $\pm$ 13.3 (18-73)
Gender (male/female), n(%)	37/9 (80.4/19.6)
Body surface area, m <sup>2</sup>	1.74 $\pm$ 0.19 (1.4-2.3)
Etiology, n(%)	
Congenital	3 (6.5)
Rheumatic	24 (52.2)
Degenerative	19 (41.3)
Comorbidities, n(%)	
Systemic hypertension	6 (13)
Diabetes mellitus	3 (6.5)
Peripheral arterial disease	2 (4.3)
Preoperative symptoms, n(%)	
Dyspnea	35 (76)
Angina	20 (43.4)
Syncope	10 (21.7)
New York Heart Association functional class, n(%)	
II	7 (15)
III	29 (63)
IV	10 (22)
Rhythm, n(%)	
Sinus rhythm	40 (86.9)
Atrial fibrillation	6 (13.1)
Data are expressed as mean $\pm$ standard deviation (range) for continuous variables and n (%) for categorical variables	

ventricular internal diameter, interventricular septal thickness and posterior wall thickness (8). Left ventricular mass index (LVMI) was calculated by dividing left ventricular mass by body surface area (derived from the height and weight). Stress echocardiography with dobutamine in presence of low transvalvular gradients was performed in 14 patients to distinguish severe LV dysfunction and real low transvalvular gradients.

### Surgical data

An aortic valve replacement using a mechanical prosthesis was performed under moderate hypothermia and continuous isothermic retrograde hyperkalemic blood cardioplegia was used for the myocardial protection. The aortic root was enlarged in two patients and the ascending aorta was replaced in four patients. The mean cardiopulmonary bypass (CPB) time was  $100.6 \pm 34.4$  minutes (ranged from 60 to 220 min) and the mean cross-clamp (ACC) time was  $77.4 \pm 18.9$  minutes (ranged from 39 to 150 min).

### Follow-up

All survivors were retrospectively assessed. The patients were invited to ambulatory controls after telephone interviews. Of these, 34 patients were examined during a follow-up period of  $72.3 \pm 41.5$  months (range 8-158 months). The data records of four patients who died during follow-up were retrospectively reviewed from the latest ambulatory examinations of these patients. The eight patients who died during follow-up were under clinical control either at our department or at peripheral hospitals. Follow-up including an echocardiographic control was completed for all survivors.

### Definitions

Severe aortic stenosis was defined as an aortic valve area less than  $1.0 \text{ cm}^2$ , the mean gradient greater than 40 mmHg, or jet velocity greater than 4.0 m per second (9). Left ventricular dysfunction was defined as LVEF  $\leq 40\%$ . Chronic obstructive pulmonary disease was defined as the need for pharmacologic therapy for chronic pulmonary compromise or as a preoperative spirometry with a severe obstruction. Chronic renal insufficiency was defined as serum creatinine  $\geq 2 \text{ mg/dL}$ . Inotropic support was considered as the use of postoperative inotropic agents for  $>24$  hours. Early mortality was defined as death occurring within 30 days of operation, and late mortality as death occurring after that time. Long-term survival was defined as a life period after hospital discharge.

### Statistical Analysis

Statistical analysis was performed using the statistical software SPSS 12.0 for Windows (SPSS Inc, Chicago, IL). Data are expressed as mean  $\pm$  standard deviation for continuous variables and as numbers with percentages for categorical variables. Logistic regression analysis was used to assess the predictors for early mortality, and Cox proportional hazard regression analysis was used to study survival after AVR. All multivariate analyses were performed with  $p < 0.05$  as the limit on univariate analysis for entering or removing variables. Wilcoxon rank-sum test was used as appropriate for comparison of continuous variables (between preoperative and postoperative stages). Survival curve was plotted using the Kaplan-Meier method. A  $p$  value  $< 0.05$  was considered statistically significant.

## Results

### Early mortality

Early mortality was 8.6% with four patients. They required high dose inotropic support while weaning from the cardiopulmonary bypass (CPB) and died due to low cardiac output syndrome: two patients on postoperative third day, one on postoperative fourth day and one on postoperative tenth day.

### Predictors of early mortality

Predictors of early mortality were analyzed using logistic regression analysis. The following fourteen variables were analyzed: etiology, age ( $\geq 70$  years), sex, preoperative New York Heart Association (NYHA) functional class, chronic obstructive pulmonary disease, hypertension, diabetes, peripheral arterial disease, chronic renal insufficiency, need for concomitant procedures for the ascending aorta, CPB time  $\geq 120$  min, aortic cross-clamp (ACC) time  $\geq 90$  min, intraaortic balloon pump (IABP) support, inotropic support. As the result of univariate logistic regression analysis, preoperative NYHA functional class  $\geq 3$  was found to be predictive of early mortality. Patients with NYHA class  $\geq 3$  had 12.6 times (OR: 12.6; 95%CI: 1.2-131.3;  $p=0.035$ ) higher probability of early mortality than those with a lower NYHA class. However, multivariate logistic regression analysis failed to identify any independent predictor of early mortality. Advanced age, presence of comorbidities such as diabetes and hypertension, prolonged CPB and ACC times and concomitant procedures involving ascending aorta were not found to be predictors of early mortality ( $p > 0.05$ ).

### Postoperative outcomes

During the postoperative period, 24 patients required an inotropic support, and three of them required IABP. Univariate analysis revealed that the ACC time  $\geq 90$  minutes ( $p=0.006$ ) and CPB time  $\geq 120$  minutes ( $p < 0.001$ ) were associated with the increased requirement of inotropic use. Mechanical ventilation longer than 24 hours was necessary in six patients (13%), but four of them died during the early postoperative period. One patient required a permanent pacemaker implantation. The mean duration of stay in the intensive care unit was  $5.05 \pm 2.01$  days (ranged from 2 to 37 days) and in the hospital was  $14.38 \pm 7.56$  days (ranged from 5 to 113 days).

### Late outcomes

#### Late mortality

There were eight (19%) late deaths. The late deaths were cardiac in six patients and non-cardiac in two patients (carcinoma and stroke). Three of them required IABP support during the early postoperative period.

#### Survival

Kaplan-Meier survival analysis revealed that the overall 5-year survival rate was  $83.1\% \pm 5.9\%$  and 10-year survival rate was  $59.6\% \pm 10.9\%$  (Fig. 1).

#### Determinants of long-term survival

Cox proportional hazards regression analysis demonstrated diabetes mellitus (HR: 6.6; 95% CI: 1.19-36.9,  $p=0.031$ ) and

intraaortic balloon pump use (HR: 10.7; 95% CI: 2.9-39.7,  $p < 0.001$ ) to be significant predictors for late mortality.

### Echocardiographic recovery

Echocardiographic evaluation was obtained in all surviving patients at 6-month follow-up (Table 2). A positive change in LVEF was observed in 79.3% of patients and LVEF significantly improved from  $34.5\% \pm 3.9\%$  preoperatively to  $44.7\% \pm 10.4\%$  after AVR ( $p < 0.001$ ).

### NYHA functional class

Significant improvement was observed in most of the survivors. Preoperatively, 79% of patients were classified as NYHA functional class III or IV, compared with 15% after AVR ( $p < 0.001$  Fig. 2).

### Discussion

Left ventricular dysfunction is a major prognostic indicator of the outcome in patients undergoing AVR for AS (3,10,11). This group of patients constitutes the most controversial and clinically challenging patients with AS. In this study conducted on patients suffering from isolated severe AS with significant LVD, aortic valve replacement was found to be beneficial. A positive change was observed in the LVEF in 79.3% of survivors and the mean LVEF increased from 34.5% to 44.7% ( $p < 0.001$ ). Operative mortality was 8.6% and late mortality was 19%. Multivariate logistic regression analysis failed to demonstrate any predictor for early mortality, where Cox proportional hazards regression analysis demonstrated diabetes mellitus ( $p = 0.031$ ) and IABP use ( $p < 0.001$ ) as significant predictors for late mortality.

The early mortality rate observed in our study correlates with the majority of previous reports demonstrating mortality rates between 8% and 18% (3,12-16). Fuster et al (16) showed that LVMI had the worst effect on the poor prognosis, whereas the other preoperative risk factors such as chronic renal failure and

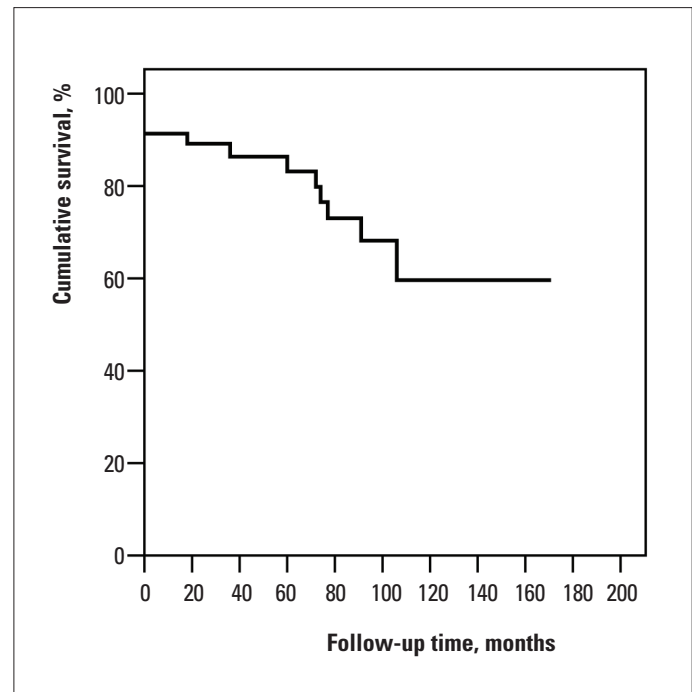
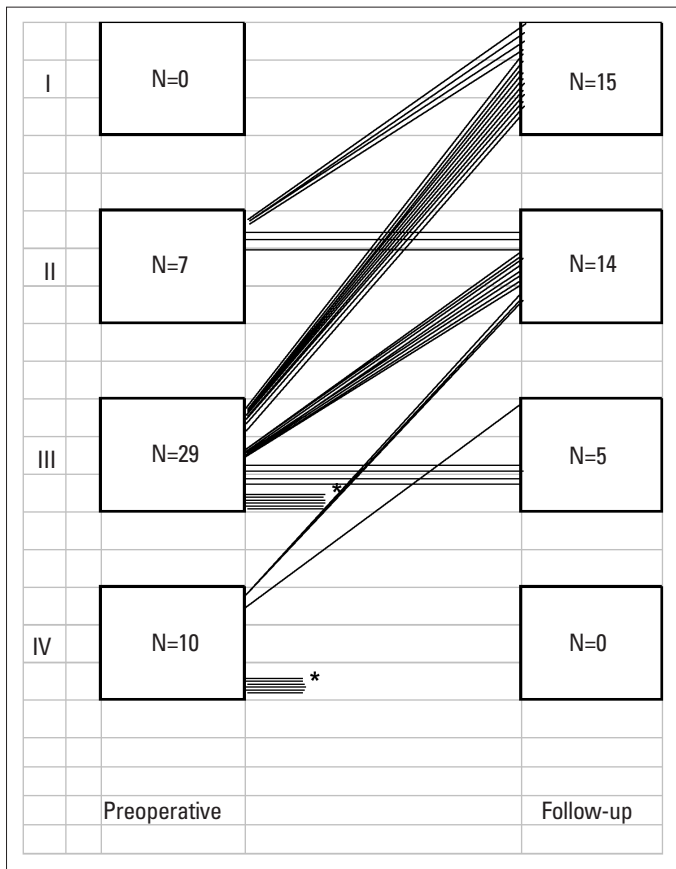


Figure 1. Kaplan-Meier survival curve

Table 2. Pre- and postoperative echocardiographic data of patients

Echocardiographic variables	Preoperative (n=46)	Postoperative (n=34)	p*
Left ventricular ejection fraction, %	34.5±3.9 (25-40)	44.7±10.4 (25-64)	0.005
Aortic valve area, cm <sup>2</sup>	0.77±0.09 (0.6-0.95)	1.64±0.45 (1.1-3.1)	0.001
Mean transvalvular gradient, mmHg	58.4±11.6 (28-78)	29.68±8.38 (15-45)	<0.001
Left ventricular			
end-systolic diameter, cm	5.15±0.81 (3.6-7.2)	4.56±0.84 (3.4-6.2)	0.1
End-diastolic diameter, cm	6.43±0.98 (5-9.5)	5.97±0.86 (4.8-7.6)	0.4
Septal diastolic wall thickness, cm	1.29±0.19 (1-1.9)	1.21±0.26 (0.8-1.8)	0.8
Posterior wall thickness, cm	1.2±0.19 (1-1.7)	1.19±0.16 (1-1.6)	0.7
Mass index, gr/m <sup>2</sup>	235.79±78.76 (118.78-507.61)	186.04±42.48 (112.13-295.75)	0.002

Data are expressed as mean ± standard deviation (range) for continuous variables and n (%) for categorical variables. \*p values of Wilcoxon rank-sum test; statistical significance is expressed as  $p < 0.05$ .



**Figure 2. Comparison of preoperative (n=46) and postoperative (n=34) (follow-up) New York Heart Association functional class**

N: number of patients; \*: deaths

prolonged CPB (>120 minutes) were associated with early mortality. In this study, gender, advanced age, presence of atrial fibrillation and concomitant diseases such as diabetes mellitus and hypertension, prolonged CPB and ACC times, concomitant procedures for the ascending aorta were not found to be predictive of early mortality. Although ACC and CPB times were quite longer in patients who underwent concomitant ascending aorta replacement, they did not increase early mortality. This can be attributed to the improved surgical and myocardial preservation techniques. Only preoperative NYHA functional class  $\geq 3$  was identified as a predictor of early mortality on univariate logistic regression analysis ( $p=0.035$ ); whereas multivariate analysis failed to identify any independent predictor of early mortality. Patients with NYHA class  $\geq 3$  had 12.6 times (OR: 12.6; 95%CI: 1.2-131.3;  $p=0.035$ ) higher probability of early mortality than those with a lower NYHA class. It can be suggested that these patients would better be referred for assessment of surgical treatment before severe LVD with symptoms (NYHA functional capacity  $\geq 3$ ) develop. Although current guidelines for treating severe AS identify the onset of symptoms as the critical point, Cleveland Clinic (4) has showed recently that relying on symptoms alone in therapeutic decision making is inadequate and higher NYHA functional class is one of the most significant risk factors for late death. That means that AVR should be performed before severe LVD develops.

Operative mortality rate is higher in certain patient groups such as those undergoing concomitant coronary artery bypass grafting (2, 17). Therefore, it is suggested that patients with severe AS and accompanying LVD should have coronary angiography and early AVR in the earliest phase of LVD even if they are asymptomatic (5, 18). Unlike most other studies in the literature which included patients with CAD, we excluded those patients with CAD to evaluate the isolated effect of AVR on ventricular function, mortality and morbidity in isolated AS. Left ventricular dysfunction may occur due to afterload mismatch in patients with severe AS, and AVR results in an improvement of LVEF in these patients. Development of fibrosis leads to irreversible myocardial dysfunction and reduces potential benefits of AVR in patients with aortic stenosis. However, in patients with concomitant CAD, previous myocardial infarctions and the presence of hibernation may cause LVD and these patients should be evaluated carefully before operation. We believe that it is difficult to interpret the effect of AVR on the recovery of LVD in the presence of preoperative myocardial hibernation. Therefore, in order to prevent such confusion and assess the effect of surgery on the recovery of the left ventricular function in patients with isolated severe AS and LVD, we excluded patients with CAD.

The overall 5-year survival rate was  $83.1\% \pm 5.9\%$  and 10-year survival rate was  $59.6\% \pm 10.9\%$ . Five-year survival rate complies with the rates (range 49%-75%) reported in other studies (4, 12, 14, 15). These findings signify the importance of AVR for the improvement of late survival of this patient group and support the suggestion that severe AS rarely has clinical contraindications to surgery for cardiac reasons (9). We also observed that 50% of the late deaths showed no improvement of LVEF after the operation. This can be explained by the fixed myocardial damage instead of afterload mismatch, which results in the same mortality rate seen in non-operated patients. The proper use of dobutamine stress test may help to differentiate these patients who would benefit from surgery (7, 19). Diabetes mellitus was found to be a significant risk factor for late death in our study like others (1, 4, 6). Different from the other studies we found that IABP support was a significant risk factor for late death. We can explain that preoperatively severe LVD may cause low cardiac output syndrome after surgery and result in a need for excessive inotropic and IABP supports. Preoperative left ventricular function is accepted as a key determinant of surgical outcome in patients with severe AS, while the development of left ventricular hypertrophy in terms of an increase in LVMI is recognized as an independent cardiac risk factor (16, 20).

Patients with severe AS constitute a challenging group. Patients with low LVEF have two different reasons for LVD: afterload mismatch, which generally respond well to surgery and immediately normalizes left ventricular afterload; and advanced left ventricular systolic dysfunction, which causes a high operative risk group. Increased LVMI could be responsible of higher mortality by means of contractile impairment, diastolic dysfunction, abnormalities of coronary flow reserve or cardiac arrhythmias. A significant decrease in LVMI after operation shows better survival (16, 20). In our study, survivors had a significantly decrease in LVMI after operation. Serial

measurements of left ventricular mass may be helpful for assessing the efficacy of therapeutic intervention and in determining the timing of surgery for patients with chronic aortic valve disease.

### Limitations of the study

This study is limited by its retrospective nature and sample size. Dobutamine stress echocardiography is not performed routinely in our unit, but only when other preexisting comorbidity indicates a need to demonstrate recoverable myocardium and we have only used to risk stratify patients and not to include or exclude surgical candidacy.

### Conclusion

Left ventricular ejection fraction and symptoms improve after AVR in patients with severe isolated AS and LVD with acceptable operative mortality and satisfactory long-term survival. Particularly, patients with severe AS and LVD should undergo AVR in the earliest phase of LVD, because preoperative worsening of functional capacity can increase operative mortality. Likewise, impaired left ventricular function affects long-term survival, especially the need for IABP support is one of the important predictors for late death.

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