Fate of aortic bioprostheses: An 18-year experience

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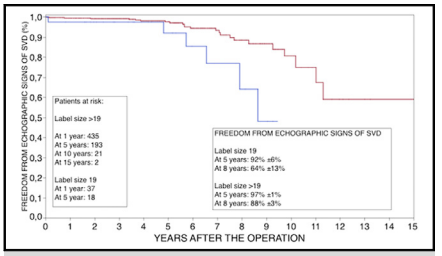
ABSTRACT

Objective: To report our experience in aortic valve replacement with the Mitroflow (Sorin, Vancouver, Canada) aortic bioprosthesis.

Methods: We retrospectively reviewed all patients who underwent aortic valve replacement with a Mitroflow bioprosthesis at our institution from January 1994 to December 2011. No exclusion criteria were retained. Patients were followed yearly. Echocardiography follow-up was performed systematically before the hospital discharge and annually by patients' cardiologists.

Results: Seven hundred twenty-eight patients (mean age, 76 ± 6 years; range, 33-91 years) underwent aortic valve replacement with Mitroflow 12A or LX model and were included in this analysis. 30-day mortality for nonemergent isolated aortic valve replacement was 5.5%. Eight patients (1%) underwent reoperation for structural valve deterioration (SVD) and 30 patients (5.8%) presented echocardiographic signs of SVD. Actuarial freedom from reoperation for SVD was 99% ± 0.5% and 95% ± 5% at 10 and 15 years. Actuarial freedom from echocardiographic signs of SVD was 77% ± 5% and 56% ± 11% at 10 and 15 years, respectively. At the univariate analysis, only the mean gradient at discharge ($P = .0200$), the prevalence of size 19 ($P = .0273$), and severe patient–prosthesis mismatch ($P = .0384$) were significantly different in patients developing SVD at follow-up. Freedom from echocardiographic signs of SVD at 8 years were 88% ± 4% and 64% ± 13% in patients with a Mitroflow > 19 and Mitroflow 19, respectively (log-rank test, $P = .0056$; Wilcoxon test, $P = .0589$).

Conclusions: Overall outcomes were satisfactory. However the risk of early SVD seems higher for the Mitroflow size 19. This size should be reserved for applications when annulus enlargement is risky or there is an anatomic contraindication to sutureless or stentless valve. (J Thorac Cardiovasc Surg 2016;151:754-61)



Freedom from structural valve deterioration (SVD) according to size of prosthesis.

Central Message

Overall outcomes were satisfactory. However the Mitroflow size 19 (Sorin, Vancouver, Canada) seems vulnerable to a higher risk of early degeneration.

Perspective

Mitroflow size 19 (Sorin, Vancouver, Canada) is presently the smallest biological stented valve available on the market. It is broadly employed in small annulus applications. However, Mitroflow size 19 seems vulnerable to a higher risk of early structural valve deterioration. This size should be reserved for applications when the annulus enlargement is risky or when there is an anatomic contraindication to sutureless or stentless valve.

See Editorial Commentary page 762.

Supplemental material is available online.

Important demographic changes are taking place in Western populations. In the European Union, according to Statistical Office of the European Communities,[1] the octogenarian population has grown from 1.5% in 1960 to 4.8% in 2007 and is expected to reach 7.4% in 2030 (Appendix E1).

As a result of the ageing population, during the past 15 years a higher number of elderly patients have been referred to cardiac surgery for aortic valve replacement. In these patients, biological prostheses are strongly recommended because they offer freedom from anticoagulant treatment and potentially lifelong durability resulting in a better event-free survival when compared with mechanical prostheses. Among the biological aortic valve prostheses currently available, the present design of the Mitroflow valve was introduced 1992 by the model 12A (Sorin, Vancouver, Canada). It is a bovine pericardial prosthesis specifically designed for improved hemodynamic parameters in small aortic annuli. In 2006, the model 12A was replaced by the LX without any modification in the design

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Abbreviations and Acronyms
NSD = nonstructural dysfunction
PPM = patient–prosthesis mismatch
SVD = structural valve deterioration

and in the material components, so that model 12A and model LX can be considered the same prosthesis.

The fate of Mitroflow bioprosthesis is unclear. Although published series reported satisfactory hemodynamic parameters and long-term durability,[2-6] Senage and colleagues[7] recently reported frequent early structural valve deterioration (SVD) and poor long-term survival after aortic valve replacement with the Mitroflow bioprosthesis and they recommended careful monitoring and urgent redo surgery in patients with severe SVD even in asymptomatic patients.

We report our experience in aortic valve replacement with the Mitroflow aortic bioprosthesis to analyze survival, occurrence of SVD, nonstructural valve dysfunction, and endocarditis after surgery.

MATERIALS AND METHODS

We retrospectively reviewed all patients who underwent aortic valve replacement with the Mitroflow bioprosthesis (12A and LX models) at our institution from January 1994 to December 2011. No exclusion criteria were retained. Morbidity and mortality after the aortic valve replacement were reported according the latest guidelines.

SVD was defined as a dysfunction or deterioration of the prosthesis (exclusive of thrombosis or infection) determined by reoperation or echocardiographic investigation. At the echocardiographic follow-up, the finding of a mean transprosthetic gradient >40 mm Hg or an aortic regurgitation more than moderate was considered SVD.

Nonstructural dysfunction (NSD) was defined as any abnormality not intrinsic to the valve itself that results in stenosis or regurgitation of the prosthesis (exclusive of thrombosis or infection).

Diagnosis of endocarditis was based on evidence of abscess, paravalvular leak, pus, vegetation at the reoperation (confirmed as secondary to infection by histologic or bacteriologic studies) or in absence of reoperation by the Duke Criteria for endocarditis.

The follow-up ended in April 2014. Patients were followed either by yearly outpatient visit or by telephone and letter to the referring physician. Echocardiography follow-up was realized systematically before hospital discharge and annually by patients' cardiologists.

Statistical Analysis

Statistical analysis was performed with JMP statistical analysis software (SAS Institute Inc, Cary, NC). Continuous variables are presented as means ± standard deviation and categorical variables are expressed as frequencies.

For the univariate analysis, continuous variables were compared with the Student *t* test or the Wilcoxon rank-sum test. Categorical variables were compared by means of the χ^2 test or Fisher exact test (2 tailed) if the expected count in any cell was <5.

Completeness of the follow-up was calculated as the ratio of total observed person-time to potential person-time of follow-up to the closing date of the study (C index).[8] Survival was determined by the Kaplan-Meier method and is expressed as the proportion ± standard error. Survival was compared by log-rank and Wilcoxon tests.

RESULTS

Populations

During the study period, 728 patients (mean age, 76 ± 6 years; range, 33-91 years) underwent aortic valve replacement with Mitroflow model 12A or LX and were included in this analysis. Demographic characteristics, patients' history, and operative data are detailed in Table 1. Twenty-six percent of patients were octogenarians and 2% of patients were aged 60 years or younger. Half of patients were in New York Heart Association functional class III or IV. Indication for aortic valve replacement was symptomatic aortic stenosis in 91% of patients (661 patients) and pure aortic regurgitation in 9% of patients (67 patients). In 19 patients (2.5%) the aortic regurgitation was related to endocarditis and in 2 patients (0.3%) to a leaflet prolapse because of type A aortic dissection. Four percent of patients underwent emergency surgery. The left ventricular ejection fraction was unpaired in 20% of patients. Half of patients underwent concomitant procedure. No patients had an enlargement of the aortic annulus. Table 2 details distribution of prosthesis size in our population. The majority of patients received size 21 or size 23, but size 19 was also frequent (10% of patients). Based on the in vivo effective orifice area values given by the manufacturer of the Mitroflow valve, 4% of patients (n = 30) had severe patient–prosthesis mismatch (PPM). Severe PPM was observed mostly with sizes 19 and 21 mm (Table 2).

Survival and Morbidity

Early mortality was 10.3% (75 patients), 12.5% (91 patients), and 13.7% (100 patients) at 30, 60, and 90 days, respectively, after surgery. Thirty-day mortality for nonemergent isolated aortic valve replacement was 5.5% (20 of 359 patients). Cardiogenic shock and multiorgan failure were the main causes of early death (Table 3).

Two hundred four patients developed at least 1 complication after the surgery. Major bleeding and cardiogenic shock were the most frequent postoperative complications. Less than 3% of patients required pacemaker implantation for permanent atrioventricular block (Table 3).

There were 230 late deaths. Median survival was 7.4 years. Actuarial survival, including early deaths, was 66% ± 2%, 33% ± 3%, and 15% ± 7% at 5, 10, and 15 years, respectively, after initial surgery (Figure 1). Actuarial survival after nonemergent isolated aortic valve replacement was 72% ± 2% and 40% ± 4.5% at 5 and 10 years, respectively, after initial surgery (Figure 1).

Reoperation

During the study period (mean follow-up, 4.3 ± 1.3 years; median follow-up, 4 years; range, 0-16.3 years; 3155.81

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