Early single-center experience in sutureless aortic valve implantation in 120 patients

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Objective: The study objective was to evaluate the safety and efficacy of sutureless self-expanding nitinol stent-frame aortic valve prostheses made of equine pericardium implanted in patients with symptomatic aortic valve disease.

Methods: We performed a retrospective analysis of 120 patients (mean age, 76.7 ± 5.9 years) who underwent isolated aortic valve replacement or in combination with other cardiovascular procedures. Preoperatively, Society of Thoracic Surgeons score was determined. Transthoracic echocardiography and clinical outcome evaluation were performed at the time of discharge and at 6, 12, and 18 months follow-up, respectively.

Results: A total of 71 of 120 patients underwent isolated sutureless aortic valve replacement (mean aortic cross-clamp time, 37 ± 11 minutes; mean bypass time, 62 ± 18 minutes). Coronary bypass grafting was performed in 30 patients. Overall mean Society of Thoracic Surgeons score was 14.8% ± 10%. Thirty-day mortality rate was 6.7% overall and 1.4% in stand-alone procedures. During a mean follow-up of 313 days, 3 more deaths occurred. The reoperation rate was 4.2%. Mean and peak transvalvular pressure gradients were 9 mm Hg (4-13 mm Hg) and 14 mm Hg (8-22 mm Hg) at discharge, respectively. In 8 patients (6.7%), permanent pacemaker implantation was necessary. No thromboembolic events or bleedings related to the bioprosthesis were observed.

Conclusions: In this large single-center experience with sutureless aortic valve replacement, the surgical procedure is shown to be safe and time-saving. In view of the excellent hemodynamic results and shortening of aortic crossclamp and bypass times, we notice advantages especially in high-risk patients. Minimally invasive access seems to be facilitated. The long-term durability of this prosthesis has yet to be determined. (J Thorac Cardiovasc Surg 2014;147:370-5)

Despite the recent introduction of various alternative approaches, surgical treatment of the aortic valve represents the gold standard of treatment in case of severe and symptomatic valve disease. This is also proven for various patients with multiple comorbidities and high perioperative risk, for example, older patients and patients with a distinct prosthesis–patient mismatch.[1-3] Various surgical approaches to enhanced treatment of the diseased aortic valve have been developed in the last decade, ranging from aortic valve repair to stentless prosthesis and complex aortic root surgery.[4-6]

Numerous studies have shown pressure gradients across the implanted prosthesis to be crucial for mass regression and restoration of left ventricular function and, consequently, long-term survival.[7,8] Stentless substitutes have been shown to be surgically more challenging but result in superior hemodynamics because of a larger effective orifice area and omission of the obstructive elements of the stented bioprosthesis. In this context, the replacement of the aortic valve with a sutureless prosthesis held in place by radial forces represents an interesting idea. The symmetric pericardial prosthesis is mounted onto a nitinol frame, which guarantees optimal orientation because of its memory effect.[9] This new technique offers complete removal of the diseased aortic valve and calcifications under vision in combination with avoiding placement and tying of sutures in the aortic annulus, facilitating minimally invasive access, decreasing surgical trauma, and providing hemodynamic benefits through its unique design.

Various reports have been published on the initial experience in relatively small cohorts of selected patients, mostly with isolated aortic valve stenosis.[10-12] The current study reports on the largest single-center experience in sutureless implantation of the Enable aortic bioprosthesis (Medtronic, Inc, Minneapolis, Minn) in unselected patients with respect to their clinical outcome and hemodynamic performance for up to 18 months postoperatively.

MATERIALS AND METHODS

Patients

Between July 2010 and March 2012, 120 patients were included in this study. Inclusion criteria were severe, symptomatic aortic valve disease, New York Heart Association function class II or higher, and scheduled for surgical valve replacement. All patients gave written informed consent

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Abbreviations and Acronyms
AVR = aortic valve replacement
TEE = transesophageal echocardiography

except in case of emergency. Detailed patient characteristics are listed in Table 1.

Sutureless Aortic Valve Prosthesis

The Enable sutureless aortic prosthesis consists of 2 main parts: the original stentless 3F biological valve made of equine pericardium with 3 symmetric sinuses that are incorporated into a nitinol stent frame. This material returns to its original shape when it is exposed to body temperature while maintaining the correct orientation of the pericardial leaflets.

Operative Technique

Cardiopulmonary bypass and cardioplegic arrest are established in routine fashion after median or partial sternotomy. In selected patients with a minimally invasive approach, a small right anterolateral minithoracotomy approximately 7 cm in length is performed and cannulation for cardiopulmonary bypass is installed via femoral cannulation. Because of the height of the nitinol stent of the prosthesis, a transverse aortotomy at least 3.5 cm above the origin of the ostium of the right coronary artery is mandatory. The diseased native aortic leaflets are excised carefully without injuring the annulus. Precise sizing of the aortic annulus is crucial. The prosthesis chosen is then rinsed for 30 seconds 3 times before placing it into ice-cold water. When malleable, the prosthesis is wrapped around a plastic bar and mounted onto a cross-action forceps.

A double-armed 4-0 polypropylene suture is placed into the nadir of the noncoronary sinus and the corresponding site at the upper flange of the Enable ring. The folded Enable prosthesis is then positioned into the aortic annulus supported by the guiding suture. After removal of the forceps, the stent is unfolded and aligned to the remaining aortic annulus. Meticulous and precise placement of the valve prosthesis along the aortic annulus is absolutely mandatory for successful deployment. Correct positioning is verified followed by application of warm water causing the nitinol stent to regain its original shape.

After weaning from cardiopulmonary bypass with cannulas still in place, transesophageal echocardiography (TEE) is performed to evaluate correct positioning of the prosthesis and to exclude paravalvular leakage. In patients with concomitant cardiac procedures, placement of the Enable prosthesis is performed as the last procedure.

Follow-up

All data related to the clinical outcome of the patient and the performance of the Enable prosthesis were collected. Thereby, adverse events were divided into early (within 30 days postoperatively) and late complications (after 30 days).

Before discharge, every patient underwent investigation of the Enable prosthesis by 2-dimensional transthoracic echocardiography. Hemodynamic parameters, such as transvalvular peak and mean pressure gradients, and effective orifice area were determined; these echocardiographic examinations were repeated 6, 12, and 18 months after surgery, respectively.

Statistical Analysis

For general demographic, clinical, and operative data, descriptive statistical methods were used and expressed as mean ± standard deviation. Categoric variables are presented as numbers with percentages.

RESULTS

Of the 120 patients, the majority was male (81/120; 67.5%). The mean age at the time of implantation was 76.7 ± 5.9 years (range, 64-90 years). More than 90% of the patients were in New York Heart Association class III and IV. The foremost cause for valve replacement was severe stenosis due to degenerative or rheumatic valve disease (110/120; 91.7%). Ten patients presented with severe pure aortic insufficiency as the underlying valve pathology. In 3 of these patients, valve replacement was necessary because of acute and subacute endocarditis. Detailed patient demographics are depicted in Table 1.

The overall study patients' mean logistic European System for Cardiac Operative Risk Evaluation was 20.71% (range, 2%-90%), and the mean Society of Thoracic Surgeons score was 14.78% (range, 2%-76%) for overall predictive mortality. However, for patients with isolated aortic valve replacement (AVR) the predictive risk scores were slightly lower (16.3% and 12.1%, respectively) (Table 2).

Isolated implantation of the Enable prosthesis in the aortic position was performed in 71 patients (59.2%). Although two thirds of those underwent a full sternotomy, a less-invasive approach was chosen in the remaining patients undergoing isolated AVR: partial sternotomy (n = 20) or anterolateral minithoracotomy (n = 4) in selected patients.

A total of 49 patients underwent concomitant surgical procedures, with coronary bypass surgery being the most frequent (30/49; 61.2%). The number of bypass grafts ranged from 1 to 4 arterial and venous grafts per patient. The remaining patients in the concomitant group (19/49 patients; 38,8%) underwent various concurrent surgeries, listed in Table 3.

In the isolated AVR group, mean cardiopulmonary bypass time was 62 ± 18 minutes (range, 39-141 minutes) and mean crossclamp time was 37 ± 11 minutes (range, 18-69 minutes). In the group of patients who underwent concomitant procedures, crossclamp and bypass times were mainly dependent on the extent of the additional procedures and were on average 47 ± 19 minutes (range, 18-134 minutes) and 80 ± 39 minutes (range, 39-322 minutes), respectively.

All available valve sizes were implanted in patients in this study, with the majority of patients receiving a 23- or 25-mm valve. The valve size distribution was as follows: 19 mm (n = 2), 21 mm (n = 18), 23 mm (n = 48), 25 mm (n = 32), 27 mm (n = 18), and 29 mm (n = 2).

A repeat aortic crossclamping was necessary intraoperatively in 10 patients because of paravalvular leakage (n = 7) and acute migration into the left ventricle (n = 2) or into the ascending aorta (n = 1) assessed by TEE while cannulas for cardiopulmonary bypass were still in place (Table 4). In patients with intraoperative paravalvular leakage (n = 7), the reasons for repeat crossclamping of the aorta were incorrect size in 3 patients and irregular annulus (ie, significantly different size and level of the 3 sinuses) in 4 patients, leading to improper positioning. A different size of the same type of