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Early Outcomes of Sutureless Aortic Valves

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Background: In elderly high-risk surgical patients, sutureless aortic valve replacement (AVR) should be an alternative to standard AVR. The potential advantages of sutureless aortic prostheses include reducing cross-clamping and cardiopulmonary bypass (CPB) time and facilitating minimally invasive surgery and complex cardiac interventions, while maintaining satisfactory hemodynamic outcomes and low rates of paravalvular leakage. The current study reports our single-center experience regarding the early outcomes of sutureless aortic valve implantation. ***Methods:*** Between October 2012 and June 2015, 65 patients scheduled for surgical valve replacement with symptomatic aortic valve disease and New York Heart Association function of class II or higher were included to this study. Perceval S (Sorin Biomedica Cardio Srl, Sallugia, Italy) and Edwards Intuity (Edwards Lifesciences, Irvine, CA, USA) valves were used. ***Results:*** The mean age of the patients was 71.15±8.60 years. Forty-four patients (67.7%) were female. The average preoperative left ventricular ejection fraction was 56.9±9.93. The CPB time was 96.51±41.27 minutes and the cross-clamping time was 60.85±27.08 minutes. The intubation time was 8.95±4.19 hours, and the intensive care unit and hospital stays were 2.89±1.42 days and 7.86±1.42 days, respectively. The mean quantity of drainage from chest tubes was 407.69±149.28 mL. The hospital mortality rate was 3.1%. A total of five patients (7.69%) died during follow-up. The mean follow-up time was 687.24±24.76 days. The one-year survival rate was over 90%. ***Conclusion:*** In the last few years, several models of valvular sutureless bioprostheses have been developed. The present study evaluating the single-center early outcomes of sutureless aortic valve implantation presents the results of an innovative surgical technique, finding that it resulted in appropriate hemodynamic conditions with acceptable ischemic time.

Key words: 1. Prosthesis design
2. Heart valve prosthesis implantation
3. Bioprosthesis

INTRODUCTION

The increase in life expectancy among the general population has resulted in an increase in the prevalence of patients with valvular heart disease eligible for aortic valve replacement (AVR) [1]. The most effective treatment for patients with severe symptomatic aortic stenosis is surgical replacement of the valve. Valve replacement improves left ventricular (LV) systolic and diastolic function by reducing LV hypertrophy, and thereby results in better clinical outcomes [2]. Given the increasing number of comorbidities and the increasing age of patients, a tendency has emerged to use biological valve implants, avoiding the need for long-term anticoagulation therapy [3]. In comparison with stented biopro-

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stheses and mechanical valves, stentless bioprostheses provide a significant reduction in transvalvular pressure gradients. However, they are more difficult to insert, with increased cross-clamping time [4].

AVR with any kind of bioprosthesis is the preferred method, especially in older patients, due to satisfactory hemodynamic performance and postoperative durability without warfarin-related complications [2]. Transcatheter aortic valve implantation (TAVI) procedures have been developed and extensively used in high-risk patients considered to be ineligible for standard surgery using cardiopulmonary bypass (CPB). However, it remains necessary to improve the quality and safety of this procedure due to the potential for serious complications, such as pacemaker implantation, paravalvular leakage (PVL), and a high incidence of neurologic events [5].

As a cardiac valve substitute, sutureless prostheses reduce the need for sutures after annular decalcification, thereby reducing aortic cross-clamping and CPB duration and facilitating a minimally invasive approach [6]. Sutureless aortic bioprosthesis implantation is a feasible alternative for high-risk patients with aortic valve disease [7]. The current study reports our single-center experiences regarding the early outcomes of sutureless aortic valve implantation.

METHODS

1) Patients

Between October 2012 and June 2015, 65 patients were included in this study. The inclusion criteria were severe symptomatic aortic valve disease, New York Heart Association function of class II or higher, and being scheduled for surgical valve replacement. All patients gave written informed consent except in cases of emergency treatment. This study was approved by our local ethics committee.

Three different rapid deployment valves are currently approved for clinical use in Europe: the Enable (Medtronic, Minneapolis, MN, USA), the Perceval S (SorinBiomedica Cardio Srl, Sallugia, Italy), and the Edwards Intuity (Edwards Lifesciences, Irvine, CA, USA) valves. Several thousand patients have been treated with these devices to date. In our study, we used the Perceval S in 28 patients (43.08%) and the Edwards Intuity in 37 patients (56.92%).

In January 2012, sutureless valves began to be marketed in Turkey. At this time, we started to use sutureless valves in high-risk patients and patients who need concomitant procedures. In high-risk groups like our population, the choice of valve must be optimal.

2) Operative technique

All procedures were performed by one expert surgeon. Under general anesthesia and orotracheal intubation, all patients undergoing AVR were placed on CPB after a minimally invasive approach or full sternotomy. Myocardial protection was achieved by the antegrade and retrograde administration of blood cardioplegic solution on induction and continued with the retrograde administration of cold-blood cardioplegic doses every 20 minutes in accordance with our institution's routine protocol, and a final warm-blood dose was administered before releasing the cross-clamp.

(1) Perceval S: After separation of the aorta from the pulmonary trunk, a transverse aortotomy was made approximately 1 cm above the sinotubular junction. After complete visualization of the valve, the leaflets were excised and the annulus was decalcified. The aortic orifice was measured with the original sizer of the bioprosthesis.

The bioprosthesis can be collapsed using a dedicated device and positioned by means of a specific delivery system. The delivery system was loaded with the collapsed stent-mounted valve and guided to its correct position by sliding it over three guiding sutures (4–0 polypropylene), positioned at the nadir level of each resected cusp. Once the delivery system was in position, the prosthesis was deployed, the guiding sutures were removed and the valve was put in place; at this point, post-dilation modeling was performed with a dedicated balloon (30 seconds at a pressure of 4 atmospheres) (Fig. 1).

(2) Edwards intuity: After separation of the aorta from the pulmonary trunk, a transverse aortotomy was made approximately 1 cm above the sinotubular junction. The valve preparation involved two one-minute washes in saline solution. The inflation device was filled with saline (a minimum of 30 mL) and a balloon catheter was attached. A braided, non-pledgeted suture was inserted as a figure-of-eight at the nadir of each aortic sinus. The suture was then passed through the sewing ring of the valve at the black markers and snared with

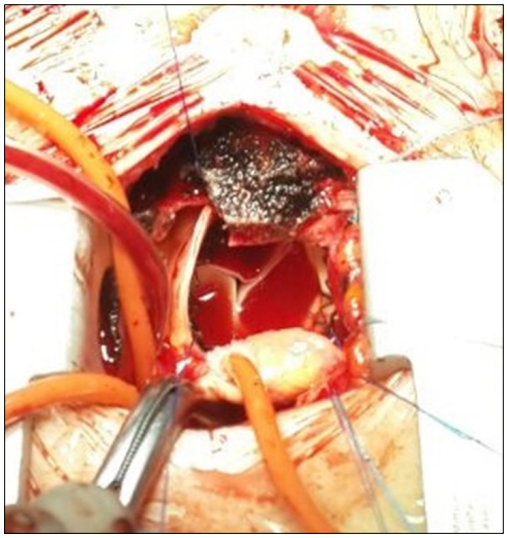

Fig. 1. Intraoperative view of the Perceval S (Sorin Biomedica Cardio Srl, Sallugia, Italy).

a tourniquet. The valve was then lowered into place in the annulus, using a gentle back-and-forth rocking motion, while pulling up on the guiding sutures. Once the valve was properly positioned, its position was secured with the suture tourniquets. The balloon catheter was inserted through the holding device and locked into place. Saline was injected until the appropriate pressure was achieved (between 3 and 5 atmospheres, depending on the valve size). The target inflation pressure was maintained for 10 seconds and then the balloon was deflated. The three prolene sutures on the valve holder were cut and the entire holding device and balloon were carefully removed. The three guiding sutures were tied and cut. The patency of the coronary ostia was confirmed (Fig. 2).

The surgical procedure was completed with the closure of the transverse aortotomy for the Perceval S and Edwards Intuity devices or with the other possible associated procedures. In cases of associated coronary artery bypass grafting (CABG), the distal anastomosis preceded the implantation of the prosthesis but followed the aortotomy and annulus sizing. Transesophageal echocardiography was performed during the procedure to evaluate the preimplantation measurements and prosthetic function. All patients underwent transthoracic echocardiography at discharge.

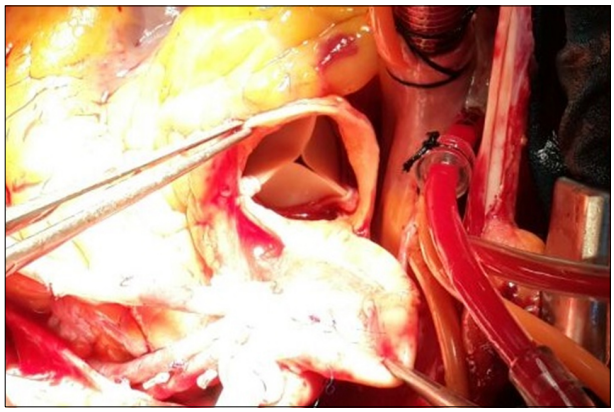

Fig. 2. Intraoperative view of the Edwards Intuity (Edwards Lifesciences, Irvine, CA, USA).

3) Statistical analysis

Statistical evaluation was performed using SPSS ver. 16.0 (SPSS Inc., Chicago, IL, USA). The results were reported as mean±standard deviation for quantitative variables and as percentages for categorical variables, and the groups were compared using the paired-samples t-test for continuous variables. Kaplan-Meier curves were used for survival analysis. All p-values <0.05 were considered to indicate statistical significance.

RESULTS

From October 2012 and June 2015, we inserted sutureless aortic valves in 65 patients. Their mean age was 71.15±8.60 years. Forty-four (67.7%) of them was female. The average preoperative LV ejection fraction was 56.9±9.93. The demographic details of the patients are summarized in Table 1.

The operative and postoperative data are summarized in Table 2. The Edwards Intuity was used in 37 patients (56.92%) and the Perceval S was used in 28 patients (43.08%). The CPB time was 96.51±41.27 minutes and the cross-clamping time was 60.85±27.08 minutes. The intubation time was 8.95±4.19 hours, and the intensive care unit (ICU) and hospital stays were 2.89±1.42 days and 7.86±1.42 days, respectively. The mean quantity of drainage from the chest tubes was 407.69±149.28 mL. The operative and postoperative variables of the AVR patients are also given in Table 2. No patients required early postoperative re-exploration due to car-

diac tamponade, bleeding, or any other reason. No serious bleeding, need for excessive blood transfusion, or thromboembolic complications occurred.

The additional procedures are summarized in Table 3. The preoperative and postoperative echocardiographic variables are given in Table 4. The postoperative hemodynamic measurements were favorable, with low peak and mean gradients. The preoperative maximum aortic gradient was 70.90±24.91 mmHg and the postoperative maximum aortic gradient was 19.92±3.93 mmHg (p=0.000). The preoperative mean gradient was 44.46±15.83 mmHg and the postoperative mean gradient was 8.43±2.76 mmHg (p=0.000). No statistically significant differences were found between the preoperative and postoperative values of the ejection fraction and the LV end diastolic and systolic diameters.

Two patients (3.1%) died during their hospital stay. One of them was an 80-year-old man who died on the eighth day due to acute renal failure and the other was an 85-year-old woman who died on the third day. She underwent an urgent repeat AVR after a TAVI procedure due to acute aortic insufficiency. A total of five patients (7.69%) died during follow-up. The mean follow-up time was 687.24±24.76 days. The one-year survival rate was over 90%. During follow-up, no patients had any kind of atrioventricular conduction block in need of transient or permanent pacemaker placement, and none underwent reoperation due to bioprosthesis dysfunction.

Table 1. Preoperative and perioperative characteristics of the patients (sutureless valves, n=65)

Characteristic	Value
Gender	
Female	44 (67.7)
Male	21 (32.3)
Age (yr)	71.15±8.60
Body surface area (m^2)	1.70±0.18
Ejection fraction (%)	56.9±9.93
New York Heart Association class	2.83±0.6
Canada classification score	2.77±0.63
EuroScore II	2.79±1.52
Hypertension	44 (67.7)
Diabetes mellitus	16 (24.6)
Smoke	15 (23.1)
Cerebrovascular disease	6 (9.2)
Peripheral vascular disease	0
Carotid artery disease	3 (4.6)
Chronic obstructive pulmonary disease	7 (10.8)
Renal failure	1 (1.5)

Values are presented as number (%) or mean±standard deviation.

Table 3. Additional procedures (sutureless valves, n=65)

Variable	Value
CABG	20 (30.77)
Mitral ring annuloplasty+CABG	1 (1.54)
Ascending aortic surgery	3 (4.62)
Ascending aortic surgery+CABG	3 (4.62)
Mitral valve replacement	1 (1.54)

Values are presented as number (%).
CABG, coronary artery bypass grafting.

Table 2. Operative and postoperative variables

Variable	Sutureless valve (n=65)	Isolated sutureless valve (n=37)	Conventional aortic valve replacement (n=69)
Operation time (min)	212.48±65.19	190.03±55.95	345±101.85
Cardiopulmonary bypass time (min)	96.51±41.27	67.22±20.57	173.04±63.03
Cross-clamping time (min)	60.85±27.08	48.86±19.43	105.50±41.40
Intubation time (hr)	8.95±4.19	8.47±4.34	9.80±4.15
Inotropic agent	35 (53.8)	13 (35.1)	30 (43.0)
Drainage (mL)	407.69±149.28	412.16±149.26	650.38±34
Erythrocyte suspension (units)	2.32±3.21	1.76±2.13	3.9±2.99
Intensive care unit stay (day)	2.89±1.42	2.23±1.12	3.25±1.25
Hospital stay (day)	7.86±1.42	6.47±1.15	12.20±3.25
Minimally invasive approach	0	5 (13.51)	0

Values are presented as mean±standard deviation or number (%).

Table 4. Echocardiographic data of patients

Variable	Preoperative	Postoperative	p-value
Ejection fraction (%)	57.08±9.92	56.92±9.55	0.788
Left ventricular end diastolic diameter (mm)	49.72±5.60	49.31±5.25	0.159
Left ventricular end systolic diameter (mm)	32.52±6.68	32.06±6.43	0.087
Interventricular septum (mm)	12.98±2.08	12.83±2.00	0.267
Posterior wall (mm)	12.66±2.01	12.57±2.02	0.458
Maximum aortic gradient (mmHg)	70.90±24.91	19.92±3.93	0.000
Mean aortic gradient (mmHg)	44.46±15.83	8.43±2.76	0.000

Values are presented as mean±standard deviation. All p-values <0.05 were considered to indicate statistical significance.

DISCUSSION

This study included 65 patients who received a sutureless aortic bioprosthesis at our institution. In the last few years, several models of valvular sutureless bioprostheses have been developed [8]. In this study, we described our experience with sutureless aortic valve prostheses, and our preliminary results demonstrated good clinical and hemodynamic outcomes.

It is well established in the cardiothoracic surgical literature that extended CPB and aortic cross-clamping durations are significant independent risk factors for mortality and morbidity in cardiac surgery [9]. A recent retrospective analysis of 979 patients with aortic valve stenosis demonstrated that aortic cross-clamping time was a significant independent predictor of cardiovascular morbidity [10]. Therefore, any technique that shortens cross-clamping or CPB time potentially decreases the risk of complications, thereby reducing long-term mortality. Sutureless AVR offered a reduction in the CPB and cross-clamping time. This is also an advantage in patients requiring an additional procedure, such as concomitant CABG in older patients. In our study, 28 patients (43.08%) underwent an additional procedure. In high-risk patients undergoing combined surgery with a prolonged surgical time, as well as in patients undergoing reintervention, the use of sutureless bioprostheses is particularly valuable due to the considerable reduction in the implantation time [11]. Choi et al. [12] studied conventional prostheses performed with a continuous suture technique to reduce CPB and cross-clamping times. They decreased the CPB and cross-clamping times to 150.6±34.6 minutes and 120.1±29.1 minutes, respectively. When compared to our study, they reported a longer time for both variables.

PVL can be a result of inadequate sizing and positioning or due to inappropriate decalcification of the annulus [4]. Correct positioning of the prosthesis can be time-consuming and must be carried out accurately. PVL must be checked by intraoperative transesophageal echocardiography. Recent evidence from TAVI trials has demonstrated a significant correlation between PVL and poorer outcomes. PVL was demonstrated to be a significant predictor of one-year mortality, even after multivariable adjustment. Unlike TAVI and similarly to conventional AVR, the sutureless AVR approach involves excision of the calcified valve and prosthesis placement under direct visualization on a still heart, which may reduce the risk of misplacement and PVL [13].

We observed significant reductions in the maximum and mean gradients postoperatively. This may reduce the risk of patient-prosthesis mismatch (PPM). In the study by Minh et al. [14] regarding sutureless valves, the mean transaortic gradient was 11.1±4.6 mmHg, similar to our findings. In a recent randomized trial comparing the Edwards Intuity sutureless valve with a conventional stented bioprosthesis, a significantly lower mean transvalvular gradient (8.5 mmHg vs. 10.3 mmHg) and lower PPM (0% vs. 15%) was found for the sutureless cohort [15].

Pollari et al. [3] found shorter ICU stays, hospital stays, and intubation times in the sutureless group then in the stented group, corresponding to our observations. Better operative variables associated with sutureless AVR resulted in shorter ICU and hospital stays and intubation times. Similarly to their study, our results also suggest a less frequent need for blood transfusions [3].

AVR with a bioprosthesis is preferred, especially in older

populations, due to its satisfactory hemodynamic performance without warfarin-related complications [2]. Recent published series of conventional AVR procedures performed in elderly patients have shown operative mortality rates ranging from 4% to 10% [16]. In our study, the hospital mortality rate was 3.1% and the one-year survival rate was approximately 90% in this high-risk population.

In our study, five patients underwent a minimally invasive approach. Sutureless AVR can be performed through a minimal incision, as demonstrated by several recently published case series that have shown excellent clinical and hemodynamic results [17].

The major limitation of this study is that it was based on data from a single institution and a very limited number of cases. There was no control group, and this was a descriptive study. This study showed only early outcomes, and it remains necessary to obtain data documenting long-term performance.

In conclusion, current evidence suggests that sutureless AVR will become the first choice of procedure in the elderly high-risk population, with its major advantages being a reduction in cross-clamping and CPB duration. This single-center experience in sutureless aortic valve implantation reflects the implementation of an innovative surgical treatment, resulting in appropriate hemodynamic conditions with acceptable ischemic time.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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