Sutureless Aortic Valve Replacement

Kenan Sever[1], Oguz Konukoglu[1], Ozgur Yildirim[1], Hakan Kilercik[2] and Denyan Mansuroglu[1]

[1]*Department of Cardiovascular Surgery, Istanbul Yeni Yuzyil University, Gaziosmanpasa Hospital, Istanbul, Turkey*
[2]*Department of Anesthesiology, Istanbul Yeni Yuzyil University, Gaziosmanpasa Hospital, Istanbul, Turkey*

ABSTRACT

Objective: To compare the results of sutureless aortic valve replacement (AVR) with the conventional method.
Study Design: A case-control study.
Place and Duration of Study: Cardiovascular Surgery Unit, Istanbul Yeni Yuzyil University, Gaziosmanpasa Hospital, Turkey, from December 2014 to December 2019.
Methodology: Patients undergoing AVR were enrolled. The inclusion criteria were severe symptomatic aortic valve disease, New York Heart Association (NYHA) class II or higher, and age >55 years. Perioperative clinical and echocardiographic outcomes were assessed in all patients.
Results: Ninety-one patients (45 women, 46 men) underwent AVR (49 sutureless, 42 conventional). The average age was 73.08 ± 7.54 years in the sutureless group and 66.26±8.63 years in the conventional group. The mean cross-clamp and cardiopulmonary bypass (CPB) times were 72.86 ± 34.09 and 91.88 ± 36.98 minutes, respectively, in the former; and 104.96 ± 41.64 and 119.81 ± 40.45 minutes, respectively, in the latter. In the sutureless group, 30 (61.2%) patients underwent additional procedures such as CABG, mitral interventions, tricuspid repair, ascending aortic surgery, and myxoma removal. Preoperative peak and mean pressure gradients decreased from 76 and 48 mmHg to 16 and 9 mmHg postoperatively in the sutureless group; and from 70.9 and 44 mmHg to 24 and 12 mmHg in the conventional group. Paravalvular leak and permanent pacemaker requirement due to AV-block rates were 6.1%. The mean ICU stay was 3.69±6.75 and 2.31±1.80 days, the mean hospital stay was 10.08±6.56 and 8.62±3.28 days, and the 30-day overall mortality rates were 8.2% and 4.8% in the sutureless and conventional groups, respectively.
Conclusion: Sutureless AVR has advantages of shorter cross-clamp time, reduced CPB duration, and postoperative aortic gradients. However, there was no advantage in terms of mortality or hospital stay. Its benefits could be more prominent in complex cases or minimally invasive surgery.

Key Words: *Sutureless valves, Aortic valve stenosis, Valve replacement.*

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INTRODUCTION

Aortic valve stenosis is the most common valve disease in an aging population; and the annual mortality expectancy in patients with severe stenosis is 30-50%.[1,2] The most effective treatment for severe aortic valve stenosis is aortic valve replacement (AVR). Clinical studies show improved left ventricular systolic and diastolic function due to the regression of left ventricular hypertrophy after aortic valve replacement.[3,4] Biologic aortic valves are preferred to reduce postoperative gradient levels and avoid complications related to warfarin use in elderly patients with aortic stenosis.

Correspondence to: Oguz Konukoglu, Department of Cardiovascular Surgery, Istanbul Yeni Yuzyil University, Gaziosmanpasa Hospital, Istanbul, Turkey
E-mail: oguzkonukoglu@yahoo.com

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Clinical reports indicate a low gradient and long-term durability with pericardial and porcine valves, with good results up to 20 years.[5] However, these valves are implanted on a stent with a Dacron graft, and a residual gradient (depending on graft bending) may occur in a narrow and calcified annulus. Bioprosthetic valves without stents have been developed to overcome these problems, which provide a greater orifice area.[6] The advantage of the stent-free structure is that it increases the effective valve area and decreases the gradient. However, their implantation is more complicated than the stented valves which leads to increased surgical cross-clamp time.[7] Transcatheter-mediated aortic valve implantation (TAVI) is recommended in elderly and high-risk patients; however, studies have shown that TAVI has high complication rates.[8] Sutureless aortic prosthetic valves developed in recent years maximize effective valve orifice area and reduce cross-clamp time.[9,10] In the sutureless implantation technique, the valve is placed without or with three stitches, resulting in a significant cross-clamp time reduction.[11,12]

These sutureless valves have changed the implantation method to the aortic annulus.[13] Indeed, such a change in tech-

nique can bring advantages and disadvantages that will be discussed below. These prostheses have been used in Turkey since 2012.

The aim of this study was to compare the short-term results of sutureless AVR with conventional AVR.

METHODOLOGY

Between December 2014 and December 2019, 49 patients (30 women, 19 men) received sutureless aortic valves; and 42 patients underwent conventional aortic valve replacement by the same surgeon. The inclusion criteria were severe symptomatic valve disease, New York Heart Association (NYHA) class II or higher, and age >55 years. All patients received informed consent forms. The sutureless method was selected in patients who have narrow and calcific aortic roots. The necessary permissions were obtained for the study from the Ethics Committee of the University.

In this study 16 Sorin Perceval valves (32.7%) and 33 Edwards Intuity valves (67.3%) were used for these patients.

A median sternotomy was performed on most patients following general anesthesia and orotracheal intubation. Unicaval venous and aortic arterial cannulation was applied to isolated cases. Bicaval venous cannulation was used in complicated cases such as concomitant tricuspid or mitral interventions. The aorta was split from the pulmonary artery. Transverse/oblique aortotomy was performed after placing the cross-clamp. The heart was arrested by applying antegrade isothermic blood cardioplegia from the coronary ostia. The process was repeated at intervals of 20 minutes until the aortotomy was closed. In complex cases, cardiac protection was achieved by retrograde cardioplegia. The aortic valve was excised, and the annulus decalcified. The valve size was measured using original valve scales.

For Sorin Perceval valve implantation, a transverse aortotomy was performed about 2 cm above the sino-tubular junction. After excision and decalcification, the valve applicator was advanced to the aortic position. The valve was expanded after verifying the appropriate positioning of the prosthesis. The applicator was taken out. A post dilatation balloon was inserted in the aortic valve and dilated for 30 seconds at a pressure of 4 atmospheres.

For Edwards Intuity valve implantation, an oblique aortotomy was performed about 1 cm above the sinotubular junction. Following excision and decalcification, three 4-0 prolene sutures were placed at the nadir of the aortic sinus. The valve was prepared by washing in saline solution for 2 minutes. The balloon inflator was filled with a 40 ml saline solution, and a balloon connection was made. The sutures (previously passed through the commissures) were passed through the lid's sewing ring and unified by snares. The guide sutures were tightened to advance until the valve was placed in the exact aortic position with the help of the valve applicator. The snares were squeesed, and the valve was fixed to its final position. The balloon inflation was achieved at pressures ranging from 3 to 5 atmospheres for at least 10 seconds, and the stabiliser ring under the valve was expanded. The guide sutures were firmly tied above the valve annular ring, and the valve applicator was taken out.

Following valve implantation, the aortotomy was closed with 4-0 or 5-0 prolene continuous sutures. After the cross-clamp was removed, the cardiopulmonary bypass was terminated following standard procedures, and epicardial pacemaker wires were placed. In the presence of coronary bypass graft surgery (CABG), distal bypasses were done before valve implantation and proximal bypasses after aortic valve implantation under cross-clamping. In the presence of additional mitral and tricuspid valve intervention, atriotomy and valve procedures were performed before aortic valve implantation. Valve position and possible leakage after implantation were evaluated with intraoperative TEE in all patients. All patients underwent transthoracic echocardiography before hospital discharge.

Demographic data, preoperative, and postoperative parameters were compiled by retrospectively accessing the data of all patients undergoing aortic valve implantation. SPSS version 22.0 (SPSS Inc., Chicago, IL, USA) was used in data analysis. Average, standard deviation, median, and (IQR: 25th percentile-75th percentile) for numerical evaluations and percentage values for categorical variables were calculated. Normality of data was evaluated by the Shapiro-Wilk test and found to be non-normally distributed; therefore, non-parametric Wilcoxon sign rank test was applied to related groups while Mann-Whitney U-test used for independent groups. All p-values <0.05 were considered to indicate statistical significance.

RESULTS

Between December 2014 and December 2019, 49 patients (30 [61.2%] females, 19 [38.8%] males) underwent sutureless AVR valve implantation. The average age was 73.08 ± 7.54 years.

In addition to sutureless AVR, 30 (61.2%) patients underwent additional procedures such as CABG, mitral interventions, tricuspid repair, ascending aortic surgery, and myxoma removal. Sorin Perceval S was used in 16 patients (32.7%) and Edwards Intuity in 33 (67.3%) patients. The average cardiopulmonary bypass time was 104.96 ± 41.64 min. (76.47 ± 24.80 min. in isolated cases), and the average cross-clamp time was 72.86 ± 34.09 min. (51.05 ± 21.69 min. in isolated cases) (Table I). The average erythrocyte suspension requirement was 3.90±2.85 units in the sutureless group (3.42 ± 1.77 units in isolated cases). The intensive care unit stay time was 1.0 (1.0-3.0) days, and the hospital discharge time was 8.0(7.0-10.0) days (Table III). Three patients underwent a revision for bleeding.

Preoperative and postoperative echocardiographic data are shown in Table II. The preoperative and postoperative ejection fractions were 59.0(49.0-60.0) and 60.0 (49.0-63.0), respectively ($p=0.388$). The preoperative and postoperative maximum aortic gradients were 76.0 (63.0-88.5) and 16.0 (13.0-20.5), respectively ($p<0.001$); the preoperative and postoperative mean aortic gradients were 48.0 (39.5-57.5) and 9.0 (7.7-11.5), respectively ($p<0.001$).

Table I: Mean values for Intraoperative and postoperative variables.

Variable	Isolated sutureless valves (n=19)	Total sutureless valves (n=49)	Conventional aortic valve replacement (n=42)
Cross-clamping time (min)	51.05±21.69	72.86±34.09	91.88±36.98
Cardiopulmonary bypass time (min)	76.47±24.80	104.96±41.64	119.81±40.45
Erythrocyte suspension (units)	3.42±1.77	3.90±2.85	3.95±7.17
Intensive care unit stay (day)	1.58±1.21	3.69±6.75	2.31±1.80
Hospital stay (day)	7.63±1.53	10.08±6.56	8.62±3.28
Minimally invasive approach	1 (5.3)	0	1 (2.4)

Table II: Echocardiographic data of patients.

Variable	Sutureless Group (n=49)	Conventional Group (n=42)	p-value
Cross clamp time (min)	. 71.0(46.5-87.5)	88.0(65.0-110.8)	0.005
Cardiopulmonary bypass time (min)	99.0(77.5-121.5)	110.5(91.5-132.8)	0.036
Aortic max gradient difference after the operation (mmHg)	59.0(48.0-72.0)	43.7(21.8-64.4)	0.003
Aortic mean gradient difference after the operation (mmHg)	39.0(29.0-47.5)	28.8(18.0-36.4)	0.004
Ejection Fraction change after the operation (%)	1.0(-5.0-6.0)	0(-4.0-5.0)	0.994
ICU stay (day)	1.0(1.0-3.0)	1.5(1.0-3.0)	0.969
Hospital stay (day)	8.0(7.0-10.0)	8.0(7.0-10.0)	0.855
Pace-maker implantation due to AV-block	3 (6.1%)	0	0.246
Postoperative aortic regurgitation >2°	4(8.2%)	0	0.121
Hospital mortality	4 (8.2%)	2 (4.8%)	0.683

Table III: Comparison of variables between sutureless and conventional group.

Variable	Sutureless Group (n=49)	Conventional Group (n=42)	p-value
Cross clamp time (min)	. 71.0(46.5-87.5)	88.0(65.0-110.8)	0.005
Cardiopulmonary bypass time (min)	99.0(77.5-121.5)	110.5(91.5-132.8)	0.036
Aortic max gradient difference after the operation (mmHg)	59.0(48.0-72.0)	43.7(21.8-64.4)	0.003
Aortic mean gradient difference after the operation (mmHg)	39.0(29.0-47.5)	28.8(18.0-36.4)	0.004
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Postoperative aortic regurgitation >2°	4(8.2%)	0	0.121
Hospital mortality	4 (8.2%)	2 (4.8%)	0.683

In one case, the patient received a Bentall operation due to aortic root rupture. In this case, death occurred in the ICU period.

Aortic valve insufficiency >2° was seen in 4 patients. One patient died in the ICU. Two patients underwent re-operation for heart failure symptoms, and one of them died after the second operation. Aortic valve insufficiency >2° was zero in the conventional control group.

Postoperative AV block that required a permanent pacemaker occurred in 3 (6.1%) patients.

Cumulative short-term mortality was 8.2% (4 patients) in the sutureless group and 4.8% (2 patients) in the conventional control group, p=0.683.

DISCUSSION

Aortic stenosis is most common in western countries with an aging population.[1] The increase in high-risk patients has led to the development of less invasive treatment options and an increasing number of cases.[14] Currently, TAVI and sutureless aortic valve replacement are highlighted as less invasive methods.[2]

Sutureless valves showed better hemodynamic results in this series in terms of gradient change (preoperative gradient-postoperative gradient) after implantation. After the operation, the maximum gradient change was 59.0 mmHg in the sutureless group and 43.7 mmHg in the conventional group (p=0.003). The mean gradient change was 39.0 mmHg in the sutureless group and 28.8 mmHg in the conventional group (p=0.004) (Table III). Studies have shown that sutureless aortic valves reveal a significant reduction of gradients postoperatively.[3,14,15] D'Onofrio *et al.* observed that transapical and sutureless valves have lower mean aortic gradients than conventional aortic valve replacements.[14]

Sutureless implantation technique is associated with a reduction in cross-clamp and total perfusion times than the conventional method, which are independent risk factors.[16] A study by Flameng *et al.* found that the average cross-clamp and total perfusion times were 22 and 46 minutes, respectively, in selected cases.[17] In a meta-analysis compiled by 12

studies, in isolated sutureless AVR patients, cross-clamp and CPB times were 33 and 57 minutes. The average cross--clamp and total perfusion times for conventional isolated AVR cases in the STS knowledge base were 78 and 106 minutes, respectively.[2] Cross-clamp and total perfusion times for isolated AVR in our patient group were 51 and 76 minutes, respectively.

In these patients, 30 patients (61.2%) underwent additional procedures such as CABG (49%), ascending aortic procedure (8.2%), MVR (6.1%), and other operations. It is expected to have longer perfusion times in multiple procedures.[18] Cross--clamp and total perfusion times were 72.86±34.09 and 104.96±41.64 minutes, respectively, in patients undergoing additional procedures in the sutureless group.

Paravalvular aortic regurgitation is seen more commonly in sutureless than in conventional aortic valve replacements.[2,3,5,19,20] The study group showed moderate/severe regurgitation in three (6.1%) patients and no regurgitation in conventional cases (p=0.121). The AV block is a known complication.[2,11,15,19,20] Three patients developed permanent AV conduction blocks requiring pacemaker implantation. There were no AV blocks in the conventional group.

Mini sternotomy provides procedural and exposure advantages in isolated AVR cases. Although the authors performed sternotomy in most of our patients, we preferred the upper mini sternotomy in our last cases for isolated sutureless AVR.

The authors started the learning curve with Edwards Intuity. Currently, they prefer to use the Sorin Perceval S valve. The main reason for this is the design of the valves. The first handicap of the Intuity valve is the broad and rigid collar under the valve. This extra-anatomic position can cause stretching of the mitral valve. One of the patients experienced aortic root rupture following blunt trauma due to the inflation of the collar. The patient received a Bentall operation and died eventually. The second handicap can be seen in late re-operations with the Intuity valve. It can be highly challenging to detach the valve in cases of infra-aortic and possible mitral adhesion of the collar. Factors that achieve success in sutureless valve implantation based on experience are no need to make too much valve resection; appropriate sizing, and avoiding barotrauma while inflating the balloon.

Median ICU stay times were longer in the sutureless group (1.0 day in sutureless, 1.5 in conventional p=0.969), and median hospital stay was the same (8.0 days in sutureless, 8.0 in conventional, p= 0.855). Although there was no statistically significant difference between ICU and hospital stay times, more than one day of mean stay in the ICU could influence the costs. Moreover, the sutureless valves' price is around three-fold that of the bioprosthetic valves in Turkey.

There was no mortality in the isolated sutureless AVR group (19 patients). In different series, isolated AVR groups had short-term mortality that could be considered satisfactory, around 3%. A mortality rate of 13.3% (4 patients) was observed among 30 non-isolated cases. Of these, two patients received re-operations. In a sutureless multi-centric study conducted in Europe, the mortality rate was 12.9% on average in non-isolated sutureless AVR cases.[21]

A mortality rate of 8.2% (4 patients) was observed in the sutureless group. The mortality rate in the conventional group was 4.8% (2 patients). However, no significant difference was detected between the sutureless and conventional groups (p=0.683). EuroSCORE 2 values of the sutureless group were significantly higher (5.51 ± 7.29 for sutureless, 2.80 ± 3.52 for the conventional group, p=0.01). It showed that a sutureless strategy was preferred in complicated cases to reduce cross-clamp times. In previous studies on conventional aortic replacement, the mortality rate was 4-10%, and factors such as advanced age, low ejection fraction, renal insufficiency, and severe aortic calcification were cited among the causes that influenced mortality.[22]

The present results are parallel or a bit worse compared to other similar publications. The cause may be the high rate of additional procedures and the euro score values than the others.[12,13,23,24]

Thus, sutureless valves offer better hemodynamic and intraoperative results, such as lower postoperative aortic gradient, shorter cross-clamp, and cardiopulmonary bypass times. However, sutureless valve selection did not change the hospital stay, ICU stay, and mortality. These variables were also higher in the sutureless group. Although it is not easy to clearly state whether these handicaps are directly related to the sutureless technique, the authors could not find convincing results that reveal superiority to conventional aortic replacement.

Sutureless valve technology has brought new dimensions to AVR. It has unique advantages and unique complications. It increases the costs, and the decision must be based on patient characteristics. The benefits could be enhanced in the presence of additional procedures or minimally invasive strategies with acceptable results.

One limitation of this study was that it was based on data from a single center with a limited number of patients. The study revealed early outcomes, and it is necessary to have more data documenting long-term results. Although age and patient characteristics were alike, the EuroSCORE 2 values for the sutureless group were higher than those for the control group.

CONCLUSION

Sutureless aortic valve replacement has advantages in shorter cross-clamp time, reduced CPB duration, and postoperative aortic gradients. However, there was no advantage

in terms of mortality or hospital stay. Its benefits could be more prominent in complex cases or minimally invasive surgery.

ETHICAL APPROVAL:
Ethical approval was obtained from the Yeni Yuzyil University Clinical Research Ethical Committee prior to the initiation of the research work.

PATIENTS' CONSENT:
Informed consent was obtained from the patients to publish the data concerning this case.

CONFLICT OF INTEREST:
The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:
KS, OK: Substantial contributions to the conception or design of the work; and the acquisition, analysis or interpretation of data for the work.
OY: Drafting the work, and revising it critically for important intellectual content.
HK: Final approval of the version to be published.
DM: Agreement to be accountable for all aspects of the work.

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