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Original Article / Özgün Makale

Early outcomes of the sutureless aortic valves versus conventional stented bioprosthetic valves

Konvansiyonel stentli biyoprotez kapaklara kıyasla dikişsiz aort kapaklarının erken dönem sonuçları

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ABSTRACT

Background: In this study, we compared the early outcomes of sutureless aortic valves versus conventional stented bioprosthetic valves.

Methods: Between October 2009 and May 2014, 46 patients (22 males, 24 females; mean age 74.74±7.35 years; range 56 to 87 years) were included. The patients were divided into two groups including 25 patients with conventional stented bioprosthetic valves in group 1 and 21 patients with sutureless aortic valves in group 2.

Results: The maximum postoperative aortic gradient was 20.1±5.5 mmHg for the sutureless group and 28.7±13.9 mmHg for the stented group (p=0.038). The mean postoperative gradient was 10.3±3.4 mmHg for the sutureless group and 15.1±8.4 mmHg for the stented group (p=0.052). No in-hospital mortality was seen in the sutureless group; however, five patients in the stented group died during the hospital stay (p=0.054).

Conclusion: Sutureless aortic valve replacement is a novel surgical treatment modality, yielding excellent hemodynamic conditions with a short ischemic time.

Keywords: Aortic valve bioprosthesis; valve replacement.

ÖZ

Amaç: Bu çalışmada, konvansiyonel stentli biyoprotez kapaklara kıyasla, dikişsiz aort kapakların erken dönem sonuçları karşılaştırıldı.

Çalışma planı: Ekim 2009 - Mayıs 2014 tarihleri arasında 46 hasta (22 erkek, 24 kadın; ort. yaş 74.74±7.35 yıl; dağılım 56 to 87 yıl) çalışmaya dahil edildi. Grup 1'de konvansiyonel stentli biyoprotez kapak ile 25 hasta ve grup 2'de dikişsiz aort kapağı ile 21 hasta olmak üzere, hastalar iki gruba ayrıldı.

Bulgular: Ameliyat sonrası maksimum aortik gradyan dikişsiz grupta 20.1±5.5 mmHg ve stentli grupta 28.7±13.9 mmHg idi (p=0.038). Ameliyat sonrası ortalama gradyan dikişsiz grupta 10.3±3.4 mmHg ve stentli grupta 15.1±8.4 mmHg idi (p=0.052). Dikişsiz grupta hastane mortalitesi gözlenmedi; ancak stentli grupta hastane yatışı sırasında beş hasta kaybedildi (p=0.054).

Sonuç: Dikişsiz aort kapak replasmanı, kısa iskemi süresi ile mükemmel hemodinamik koşullar sağlayan, yeni bir cerrahi tedavi yöntemidir.

Anahtar sözcükler: Aort kapağı; biyoprotez; kapak replasmanı.

Increased life expectancy of the overall population causes an increase in the prevalence of patients with valvular heart disease eligible for aortic valve replacement.[1] The most effective treatment for patients with severe symptomatic aortic stenosis is surgical replacement of the valve.[2,3] This is also proven for various patients with multiple co-morbidities and high perioperative risk.[2] Valve replacement improves the left ventricular systolic and diastolic function by reducing left ventricular hypertrophy, thereby, yielding improved clinical outcomes.[3]

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Aortic valve replacement (AVR) with any kind of bioprosthesis is the preferred method in elderly, particularly, thanks to satisfactory hemodynamic performance and postoperative durability without warfarin-related complications.[3] Transcatheter aortic valve implantation (TAVI) procedures have been developed and extensively used in high-risk patients who are ineligible for standard surgery using cardiopulmonary bypass (CPB). However, it seems necessary to improve its quality and safety due to the potential risks of serious complications such as pacemaker implantation, paravalvular leaks, and increased neurological events.[4]

In the high-risk patient population, replacement of the aortic valve with a sutureless prosthesis held in place by radial forces represents an interesting idea. This novel technique offers complete removal of the diseased aortic valve and calcifications, reducing surgical injuries and operating time. Sutureless aortic bioprosthesis implantation is a feasible alternative for high-risk patients with aortic valve disease.[2]

In this study, we compared the early outcomes of sutureless aortic valves versus conventional stented aortic bioprosthetic valves.

PATIENTS AND METHODS

Between October 2009 and May 2014, 46 patients (22 males, 24 females; mean age 74.74±7.35 years; range 56 to 87 years) were included in this study. Inclusion criteria were severe, symptomatic aortic valve disease, New York Heart Association (NYHA) functional class II or higher and scheduled for surgical valve replacement. A written informed consent was obtained from each patient, except from those who were in the emergency setting. The study protocol was approved by the institutional local Ethics Committee.

The patients were divided into two groups including 25 patients with conventional stented bioprosthetic valves in group 1 and 21 patients with sutureless aortic valves in group 2.

Three different rapid deployment valves are currently approved for the 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. We used Perceval S in 17 patients (80.95%) and Edwards Intuity in four patients (19.05%) in the sutureless group.

In the stented group, we used Sorin Soprano™ in 20 patients (80%) and St. Jude Trifecta in five patients (20%). Valves were chosen according to the optimal effective orifice area in respect of the body surface area of each patient.

The EuroSCORE II results were similar between both groups (2.8±1.5 for the sutureless group and 3.4±2.4 for the stented group; p=0.269). As the sutureless valves are commercially available in the Turkish market since January 2012, we have widely used the sutureless valves to reduce the operation time. Also, we have been implementing these valves in high-risk patients and those requiring additional procedures. In the high-risk patients such as our population, the valve selection should be optimal.

All procedures were performed by a single surgeon. Under general anesthesia and orotracheal intubation, all patients undergoing AVR were placed on CPB after complete sternotomy. Myocardial protection was achieved by antegrade and retrograde administration of blood cardioplegic solution on induction and maintained with retrograde administration of cold-blood cardioplegic doses every 20 minutes in accordance with the institutional routine practice. Finally, warm-blood dose was administered before releasing the cross-clamp.

In our series, we used six (28.57%) mini-extracorporeal circulation (MECC) in the sutureless group and others were conventional CPB circuit with a roller pump. Myocardial protection was achieved by antegrade potassium chloride added calafiore solution (Politecnico di Torino, Italy). If needed, it was repeated during the procedure through the left and right coronary artery orifices.

Perceval S

After the 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 size of the bioprosthesis.

This bioprosthesis was able to be collapsed through a dedicated device and positioned by means of a specific delivery system. The delivery system loaded with the collapsed stent-mounted valve was guided to its correct position by sliding it over the 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 finally in place; at this

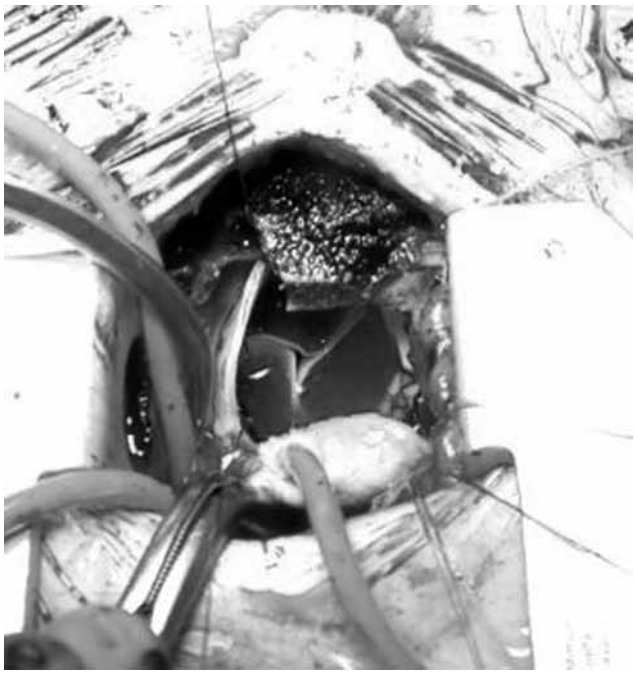

Figure 1. An intraoperative view of Perceval S.

point a post-dilation modeling was performed with a dedicated balloon (30 seconds at a pressure of 4 atmosphere) (Figure 1).

Edwards intuity

After separation of the aorta from the pulmonary trunk, a transverse aortotomy was made approximately 1 cm above the sinotubular junction. Valve preparation involved two 1 mm washes in saline solution. The inflation device was filled with saline (minimum 30 mL) and the balloon catheter was attached. A braided, non-pledgeted suture was inserted as a figure-of-eight at the nadir of each aortic sinus.

Figure 2. An intraoperative view of Edwards intuity.

The suture was then passed through the sewing ring of the valve at the black markers and snared with a tourniquet. The valve was 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. 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 (Figure 2).

Stented bioprosthesis

All patients underwent AVR through a median sternotomy using standard CPB. Myocardial protection was achieved by the infusion of antegrade blood cardioplegia and moderate hypothermia during the procedure. An oblique aortotomy extending into the noncoronary sinus was employed. The surgical technique included meticulous native annular decalcification and correct valve sizing. It was accomplished using specific sizers and accepting the largest size which fitted the decalcified annulus. The correctly sized prosthesis was subsequently implanted using interrupted pledgeted 2/0 Ethibond sutures.

The surgical procedure was completed with the closure of the transverse aortotomy for Perceval S and Edwards Intuity and oblique aortotomy for stented bioprosthesis or with the other possible associated procedures. In case of associated CABG, the distal anastomosis preceded the implantation of the prosthesis, but followed aortotomy and annulus sizing.

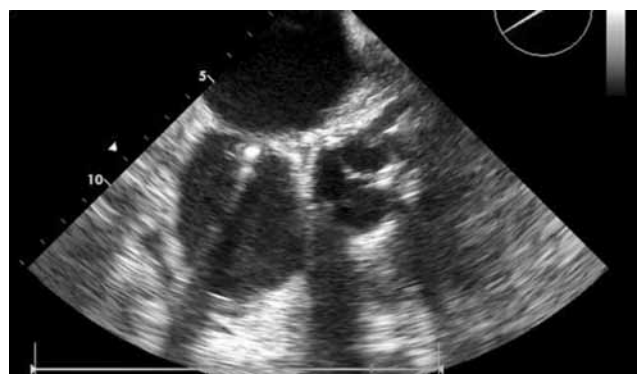

Figure 3. A transesophageal echocardiography image.

Transesophageal echocardiography was performed during the procedure to evaluate the pre-implantation measurements and the prosthetic function. All patients underwent transthoracic echocardiography at discharge (Figure 3).

Statistical analysis

Statistical analysis was performed using SPSS version 16.0 (SPSS Inc., Chicago, IL, USA) software. The data were expressed in mean±standard deviation (SD) for quantitative variables and percentages for categorical variables. The groups were compared using the Student's t-test test for continuous variables and the chi-square test (or Fisher's exact test, if required) for categorical variables. A p value of <0.05 was considered statistically significant.

RESULTS

The mean preoperative left ventricular ejection fraction was 56.9±9.9 for the sutureless group and 56±8.8 for the stented group (p=0.745). The mean ages of the sutureless group and stented group were 73.0±8.4 and 76.2±6.2, respectively (p=0.132). Baseline demographic characteristics of the patients are summarized in Table 1.

Operative and postoperative data are summarized in Table 2. Operation, CPB and cross-clamping times were statistically significantly lower in the sutureless group. The CPB time was 78.5±34.1 minutes for the sutureless group and 161.5±62.4 minutes for the stented group (p=0.000) in patients undergoing AVR without any additional procedure. Cross-clamping time was 49.2±20.9 minutes for the sutureless group and 107.9±36.4 minutes for the stented group (p=0.038). Intubation time was 8.0±2.6 hours for the sutureless group and 10.8±4.2 hours for the stented group (p=0.012). The length of intensive care unit (ICU) and hospital stays was also statistically significantly shorter in the sutureless group.

Additional procedures are summarized in Table 3. An additional root enlargement procedure (REP) was performed in two patients (8%) in the stented group to achieve an optimal orifice area. Pre- and postoperative echocardiographic variables are given in Table 4. The maximum postoperative aortic gradient was 20.1±5.5 mmHg for the sutureless group and 28.7±13.9 mmHg for the stented group (p=0.038). The mean postoperative gradient was 10.3±3.4 mmHg for the sutureless group and 15.1±8.4 mmHg for the stented group (p=0.052). Although mean and maximum postoperative gradients were statistically significant, delta values did not vary between two groups (Table 5).

No in-hospital mortality was seen in the sutureless group; however, five patients in the stented group died during the hospital stay (p=0.054). Three of them underwent additional procedures. Two had REP and

Table 1. Baseline demographic characteristics of patients

	Sutureless group (n=21)			Stented group (n=25)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Sex							0.017
Female	15	71.4		9	36		
Male	6	28.6		16	64		
Age (years)			73.0±8.4			76.2±6.2	0.132
Body surface area			1.7±0.2			1.8±0.2	0.01
Ejection fraction (%)			56.9±9.9			56±8.8	0.745
New York Heart Association			2.6±0.6			2.2±0.4	0.010
Canada classification score			2.4±0.6			2.2±0.4	0.147
EuroSCORE II			2.8±1.5			3.4±2.4	0.269
Hypertension	16	76.2		15	60		0.243
Diabetes mellitus	5	23.8		2	8		0.220
Smoke	5	23.8		4	16		0.711
Cerebrovascular disease	2	9.5		2	8		1.000
Peripheral vascular disease	0	0		1	4		1.000
Carotid artery disease	3	14.3		1	4		0.318
Chronic obstructive pulmonary disease	1	4.8		4	16		0.357
Renal failure	0	0		1	4		1.000

SD: Standard deviation; p<0.05 was considered statistically significant.

Table 2. Operative and postoperative variables

	Sutureless group (n=21)			Stented group (n=25)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Operation time (min)			205.3±75.2			341±103.9	0.000
Cardiopulmonary bypass time (min)			87.6±38.7			167.0±67.0	0.000
Cross-clamp time (min)			58.7±27.2			112.8±43.2	0.000
Intubation time (hours)			8.0±2.6			10.8±4.2	0.012
Inotropic agent	8	38.1		17	68		0.021
Drainage (mL)			452.4±244.7			900±578.6	0.003
Erythrocyte suspension (unit)			2.0±1.6			4.3±3.0	0.003
Length of intensive care unit stay (days)			2.2±1.1			3.3±2.0	0.033
Length of hospital stay (days)			7.8±1.5			14.2±5.9	0.000

SD: Standard deviation; p<0.05 was considered statistically significant.

CABG, while one had CABG alone. Other two patients died due to cerebrovascular events.

DISCUSSION

In the past few years, several models of valvular sutureless bioprosthesis have been developed.[5] Herein, we report our experience with the sutureless aortic valves prostheses versus stented bioprostheses. Our preliminary results demonstrate good clinical and hemodynamic outcomes. However, these data suggest the necessity of specific patient selection criteria and guidelines for the use of this procedure.

Aortic valve replacement with a bioprosthesis is preferred in elderly, particularly, due to its satisfactory hemodynamic outcomes without warfarin-related complications.[3] Recent published series of conventional aortic valve replacement in elderly have shown an operative mortality ranging between 4% and 10%.[6] In our study, the sutureless aortic valve was implanted after thorough surgical removal of the diseased valve, as done with conventional valve replacement. There was no in-hospital mortality in the sutureless group with a similar risk profile to the stented population. Also, REP was additionally performed in two patients in the stented group. Unfortunately, both died during the hospital stay. It is still controversial whether REP increases the operative mortality or REP is performed in already high-risk patients. In a study by, St. Rammos et al.,[7] 15 patients underwent REP and all were females without any in-hospital mortality and with good 10-year follow-up results. In Dhareshwar et al.[8] study, REP was found to be a univariate predictor of mortality; however, the multivariate analysis revealed that it was not.

Compared to the stented bioprostheses, sutureless valves can be implanted with reduced operative time, cross-clamp time, and CPB time. This can be an advantage in patients requiring additional procedures, such as concomitant CABG in elderly. In our experiences, 11 patients (52.38%) underwent an additional procedure in the sutureless group and 10 patients (40%) in the stented group. In high-risk patients undergoing combined surgery with prolonged surgical time as well as in patients undergoing re-intervention, the use of sutureless bioprostheses is particularly invaluable for the considerably reduced implantation time.[9] In our series, there were no re-interventions in both groups. In a multicenter study, Martens et al.[10] reported

Table 3. Additional procedures

	Sutureless group (n=21)		Stented group (n=25)	
	n	%	n	%
Coronary artery bypass grafting	9	42.86	7	28
Mitral ring annuloplasty + CABG	0	0	1	4
Ascending aortic surgery	1	4.76	0	0
Ascending aortic surgery + CABG	1	4.76	0	0
Root enlargement procedure	0	0	2	8

CABG: Coronary artery bypass grafting; p<0.05 was considered statistically significant.

Table 4. Echocardiographic findings of patients

	Sutureless group (n=21)	Stented group (n=25)	
	Mean±SD	Mean±SD	*p*
Preoperative			
Ejection fraction (%)	56.9±9.9	56.0±8.8	0.754
Left ventricular end diastolic diameter (mm)	47.2±5.3	49.2±6.5	0.265
Left ventricular end systolic diameter (mm)	29.4±5.8	30.7±7.3	0.499
Inter ventricular septum (mm)	12.7±2.4	14.4±2.1	0.011
Posterior wall (mm)	12±2	13.4±1.4	0.007
Maximum aortic gradient (mmHg)	67.4±24.3	74.8±20.6	0.271
Mean aortic gradient (mmHg)	42.6±17.0	47.0±13.0	0.319
Postoperative			
Ejection fraction (%)	56.6±9.1	58.3±4.5	0.470
Left ventricular end diastolic diameter (mm)	46.4±4.1	47.4±4.3	0.480
Left ventricular end systolic diameter (mm)	28.0±3.8	29.5±3.4	0.261
Inter ventricular septum (mm)	12.5±2.2	12.6±1.8	0.918
Posterior wall (mm)	11.7±2.9	11.7±1.5	0.980
Maximum aortic gradient (mmHg)	20.1±5.5	28.7±13.9	0.038
Mean aortic gradient (mmHg)	10.3±3.4	15.1±8.4	0.052

SD: Standard deviation; p<0.05 was considered statistically significant.

a mean cross-clamp time of 58±25 minutes in consistent with our findings.

Furthermore, we recorded significantly lower maximum and mean postoperative gradients in the sutureless group according to stented group, however, the reductions of both values were not significantly different. Similarly, Borger et al.[11] showed that the mean overall pressure gradients were 11±5 mmHg in the stentless valve group. In another study using sutureless valves, the mean transaortic gradient was 11.1±4.6 mmHg,[12] in consistent with our study findings.

Paravalvular leakage (PVL) can be a result of inadequate sizing and positioning or due to inappropriate decalcification of the annulus.[13] Correct positioning of the prosthesis can be time-consuming and should be carried out accurately. Any PVL should be checked by intraoperative TEE. It is beyond any doubt that a clearly visible PVL at the time of surgery demands immediate correction.[14] In our series, PVLs were observed in none of the patient groups.

Pollari et al.[14] reported shorter ICU stay, hospital stay, and intubation time in the stentless group compared to the stented group, in consistent with our study findings. In a recent retrospective analysis of approximately 1,000 patients undergoing surgical AVR, Ranucci et al.[15] reported that aortic cross-clamp time was an independent predictor of severe cardiovascular morbidity with an increased risk of 1.4% per one minute increase. Improved operative variables at the stentless group may result in shorter ICU and hospital stay and intubation time. Similar to the Pollari et al.[14] study findings, our results also suggest lower incidence of blood transfusion need.

Between two options, TAVI or surgical AVR, it still remains to be elucidated that which one is a better indication for "gray-zone" patients. D'Onofrio et al.[16] recently compared early clinical and echocardiographic outcomes of patients undergoing sutureless Perceval AVR versus TAVI using the propensity-score matching analysis. The authors showed lower mortality and PVL rates in the Perceval group. In addition, TAVI has several disadvantages

Table 5. Postoperative changes in echocardiographic gradients compared to baseline

	Sutureless group (n=21)	Stented group (n=25)	*p*
	Mean±SD	Mean±SD	
Delta maximum aortic gradient (mmHg)	47.8±23.2	49.4±24.5	0.839
Delta mean aortic gradient (mmHg)	32.3±16.2	34.4±12.9	0.677

SD: Standard deviation; p<0.05 was considered statistically significant.

such as peripheral vascular complications. In another study, Dağdelen et al.[17] reported minor vascular complications in 20% patients.

Compared to the conventional CPB, MECC was associated with lower inotropic support need, significantly lower morbidity rates, and lower incidence of stroke and respiratory insufficiency.[18] No significant changes in intraoperative or hospital mortality after MECC compared with conventional CPB were observed, either.[19] Moreover, van Boven et al.[20] reported that the use of MECC instead of conventional CPB reduced the level of oxidative stress following reperfusion after the removal of the aortic cross-clamp, as well as reduced the levels of CC16 (clara cell secretory protein)-a marker of alveolar damage. In the present study, the CPB time and cross-clamping time were statistically significantly higher in the stented group than the sutureless group. The rate of additional procedures was similar in both groups, except the AVR patients. Reduced time is likely a result of the technique facility. Reduced CPB and cross-clamp time may prevent side effects of CPB including hemolysis, ischemia, and oxidative stress, thereby, reducing the mortality and morbidity.[21]

Body surface area (BSA) was statistically larger in the stented group. In our population, there was no patient-prosthesis mismatch due to REP which was performed where applicable. Optimal orifice area was achieved in all patients. The durability of bioprosthetic valves are excellent and severe patient-prosthesis mismatch is infrequent.[22,23] In the stented group, we performed REP with Sorin Soprano valves in two patients. Although REP does not increase the surgical risk, it should be avoided in elderly with severe calcified aortic wall as in our population.[24]

The major limitation of the study was its small sample size in a single-center. Achievement of early outcomes alone can be deemed another limitation. Therefore, further long-term large-scale studies are required to confirm these findings.

In conclusion, this single-center experience in the sutureless aortic valve implantation represents a novel surgical treatment modality, yielding excellent hemodynamic conditions with short ischemic time. Although it is too soon to establish a conclusion, our experience indicates that sutureless aortic valves can be first-line treatment option for high-risk elderly.

Declaration of conflicting interests

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