Comparison of Perioperative Results of Sutureless and Conventional Valves in Aortic Valve Replacement Surgery

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ABSTRACT

Introduction: This study aimed to evaluate the early and midterm results of sutureless and conventional bioprosthetic valves in patients who underwent aortic valve replacement (AVR) due to aortic stenosis.

Patients and Methods: Patients who underwent a bioprosthetic AVR due to aortic stenosis in our institution between 2012 and 2017 were included in our study. The patients were divided into two groups on the basis of type of aortic valve prosthesis used as a sutureless valve (SU-AVR) (n= 62) and a conventional valve (C-AVR) (n= 69).

Results: The EuroSCORE II in the sutureless group was found to be significantly higher as compared to the conventional group (p= 0.0121). Patients in the sutureless group underwent more mini-incisional approaches: 22 (36%) versus 4 (6%, p= 0.0002). The mean aortic cross-clamp and cardiopulmonary bypass time were significantly lower in the sutureless group as compared to the conventional one (53.8 ± 34.2 vs. 79.2 ± 36.3 minutes and 87.5 ± 40.7 vs. 117.4 ± 66.3 minutes, p< 0.0001). The mean follow-up time was 19.5 ± 15.7 months in the sutureless group and 28.0 ± 21.0 months in the conventional group. The overall survival rate of the sutureless and the conventional group was found to be 72.6% and 78.3%, respectively, (p= 0.253) when Kaplan-Meier analysis was done.

Conclusion: Although SU-AVR patients are found to have a higher preoperative risk score compared to the conventional group, yet it can be performed with comparable mortality and morbidity to C-AVR. Therefore, SU-AVR is a promising alternative to C-AVR, especially in elderly and high-risk patients with comorbid diseases.

Key Words: Aortic stenosis; aortic valve replacement (AVR); sutureless aortic valve

Aort Kapak Replasmanı Cerrahisinde Dikişsiz Kapaklar ile Konvansiyonel Kapakların Perioperatif Sonuçlarının Karşılaştırılması

ÖZET

Giriş: Bu çalışmanın amacı, aort kapak darlığı nedeniyle aort kapak replasmanı (AVR) uygulanan hastalarda dikişsiz ve konvansiyonel biyoprotez kapakların erken ve orta dönem sonuçlarını değerlendirmektir.

Hastalar ve Yöntem: Çalışmaya kliniğimizde 2012-2017 yılları arasında aort darlığı nedeniyle biyoprotez AVR uygulanan hastalar dahil edildi. Hastalar kullanılan aort kapak protez tipine göre dikişsiz kapak (n= 62) ve konvansiyonel kapak (n= 69) olarak iki gruba ayrıldı.

Bulgular: EuroSCORE II dikişsiz grupta konvansiyonel gruba göre anlamlı derecede yüksek olarak hesaplanmıştır (p= 0.0121). Mini insizyonel yaklaşım dikişsiz grupta 22 (%36) hastaya uygulanmışken, konvansiyonel grupta 4 (%6) hastaya uygulanmıştır (p= 0.0002). Ortalama aortik kros klemp ve kardiyopulmoner baypas süreleri dikişsiz grupta konvansiyonel gruba göre anlamlı olarak daha düşük bulunmuştur (53.8 ± 34.2'ye karşı 79.2 ± 36.3 dk ve 87.5 ± 40.7'ye karşı 117.4 ± 66.3 dk, p< 0.0001). Ortalama takip süresi dikişsiz grupta 19.5 ± 15.7 ay iken konvansiyonel grupta 28.0 ± 21.0 idi. Kaplan-Meire sağkalım analizi yaptığımızda tüm nedenlere bağlı ölümler hesaba katıldığında dikişsiz kapak grubunda genel sağkalım oranının %72.6, konvansiyonel kapak grubunda ise %78.3 olduğu bulunmuştur (p= 0.253).

Sonuç: Dikişsiz AVR konvansiyonel AVR'ye göre daha yüksek preoperatif risk skoruna sahip hastalarda uygulanıyor olmasına karşın, konvansiyonel AVR ile karşılaştırılabilir mortalite ve morbidite ile uygulanabilir. Bu nedenle, dikişsiz AVR özellikle komorbid hastalıkları olan yaşlı ve yüksek riskli hastalarda konvansiyonel AVR'ye umut verici bir alternatif gibi görünmektedir.

Anahtar Kelimeler: Aort darlığı; aort kapak replasmanı; dikişsiz aort kapak

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INTRODUCTION

The incidence of senile degenerative aortic stenosis is increased with the increasing life expectancy of the older population. Symptomatic aortic stenosis could be a fatal if not treated[1]. Aortic valve replacement (AVR) is a surgical procedure where the stenotic valve is replaced with a prosthetic valve. AVR is considered as the gold standard treatment for aortic stenosis[2,3]. Biological valves that do not require anticoagulant treatment in the long term are preferred in the elderly population. The risk of structural degeneration is acceptable. New-generation sutureless aortic valves can be implanted faster than conventional biological valves. Shorter operation and cross-clamp times have been shown to decrease postoperative morbidity and mortality, especially in high-risk patients. There are limited data on literature to compare sutureless aortic valves with conventional ones for AVR. Our study aims to compare early and midterm results of conventional and sutureless bioprosthetic AVR in patients operated for isolated aortic stenosis.

PATIENTS and METHODS

Study Population

Patients who underwent bioprosthetic AVR due to aortic stenosis between 2012 and 2017 were retrospectively screened and included in the study with respect to the inclusion-exclusion criteria. Patients with sutureless bioprosthetic valves were grouped as "sutureless" (SU-AVR), and patients with stitched bioprosthesis were grouped as "conventional" (C-AVR). All patients were evaluated at the cardiology-cardiovascular surgery joint committee prior the operation to decide on the appropriate surgical intervention. High-risk patients, who were thought to have higher morbidity and mortality with conventional AVR operation, were directed to the sutureless AVR operation.

Inclusion Criteria

Patients with bioprosthetic AVR operation due to aortic stenosis and patients who signed the consent form were included in our study.

Exclusion Criteria

Patients with mechanical AVR, with transcatheter aortic valve implantation, with additional surgical intervention besides AVR, with AVR due to aortic valve insufficiency were excluded.

The study was approved by the Department of Ethics of Maltepe University (No: 2016/900/09, Date: 15/04/2016). Patients were informed about the procedure. The consent forms had been signed. The study was developed as per the Helsinki Declaration.

Data Collection

Patient data were obtained from the hospital archive, outpatient evaluation notes, patient epicrises, examination results recorded in the hospital information management system, images recorded on the echocardiography device, and telephonic conversation with patients or their relatives.

Surgical Procedure

Surgical interventions were performed by eight surgeons in Kartal Koşuyolu High Specialization Training and Research Hospital Cardiovascular Surgery Clinic.

The surgery was started with full median, mini-median sternotomy, or minithoracotomy incisions according to the predetermined planning. All operations were performed cross-clamp with the support of cardiopulmonary circulation. The aortic annulus was decalcified after excision of the aortic valve. The size of the valve was measured by valve scales. Individual pledgeted sutures were used to place conventional valves intra-annularly to remain on the aortic side. Sutureless valve implantation was done as follows: the valve was placed on its specific valve apparatus. Three guiding sutures were placed at the nadir of the valves. Guiding sutures were placed on the crimped valve, and the valve slid to its place by these sutures. The valve was released from the apparatus at the annulus. A balloon catheter was used to dilate the valve with 4 atm pressure for 30 seconds while hot serum was applied to the valve. Guiding sutures were taken at the end.

Statistical Analysis

Statistical evaluations were carried out in SAS (Version 9.3) and SPSS (Version 20.0) program. "Student t-test" or "Wilcoxon Rank Sum" test was used to compare the mean scores of the continuous scale. The t-test was used to compare scores with normal distribution, and the Wilcoxon test was used to compare scores without normal distribution. Chi-square test was used for the comparison of discrete scale scores or if the categorical scores are available; Fisher's exact probability test was used for 2 x 2 charts.

RESULTS

Preoperative Details

The demographics of the patients are given in Table 1. There are 62 patients (22 males, 40 females; mean age 71.3 ± 9.8 years) in the sutureless group and 69 (34 males, 35 females; mean age 70.3 ± 12.3 years) patients in the conventional group. EuroSCORE II was calculated as 3.5 ± 4.0 in the sutureless group, and 2.6 ± 2.6 in the conventional group. It was found to be significantly higher in the sutureless group (p= 0.01).

Operative Details

A statistically significant, more minimally invasive surgical approach was performed in the SU-AVR group. aortic cross-clamp (ACC) and cardiopulmonary bypass (CPB) times were found to be shorter in this group. Table 2 represents the valve

Table 1. Patients' preoperative parameters

	Sutureless	Conventional	p
Number of patients	62	69	
Age (a)	71.3 ± 9.8	70.3 ± 12.3	0.6509
Gender (n, %)			
Male	22 (35.5)	34 (49)	0.1166
Female	40 (64.5)	35 (51)	
*BMI (kg/m^2)	28.6 ± 4.7	27.9 ± 5.2	0.4402
*BSA (m^2)	1.7 ± 0.1	1.7 ± 0.1	0.7845
*Preoperative ECG (n, %)			
NSR	44 (76.0)	52 (80.0)	
AF	10 (17.5)	7 (11.0)	0.7287
Pace	1 (1.5)	1 (1.5)	
LBBB	3 (5.0)	5 (7.5)	
*Hypertension (n, %)	34 (58.5)	35 (54.0)	
*Diabetes mellitus (n, %)	18 (31.0)	13 (20.0)	0.7161
*Insulin usage (n, %)	13 (22.5)	3 (4.5)	0.2121
*Endocarditis (n, %)	0 (0)	5 (7.5)	**0.0058**
*COPD (n, %)	23 (39.5)	14 (21.5)	0.059
*FEV_1 (%)	79.6 ± 27.8	87.8 ± 28.1	**0.032**
*FEV_1/FVC (%)	104.2 ± 20.4	113.4 ± 15.5	0.1161
*PAD (n, %)	12 (20.5)	4 (6.0)	**0.0176**
*Stroke-SVO (n, %)	8 (14.0)	5 (7.5)	**0.0293**
*New MI (n, %)	2 (3.5)	5 (7.5)	0.38
*Presence of coronary lesions (n, %)	24 (38.5)	24 (36.5)	0.4449
*Preoperative intubation (n, %)	3 (5.0)	0 (0)	0.8558
*NYHA functional classification (n, %)			
Class 1	7 (12.0)	6 (9.0)	
Class 2	20 (34.5)	27 (41.5)	0.8619
Class 3	20 (34.5)	21 (32.5)	
Class 4	11 (19.0)	11 (17.0)	
*CCS angina score (n, %)			
Class 1	15 (26.0)	18 (27.5)	07395
Class 2	34 (58.5)	34 (52.5)	
Class 3	9 (15.5)	13 (20.0)	
*STS mortality (%)	2.9 ± 1.7	2.8 ± 3.9	0.0542
*STS morbidity (%)	18.1 ± 7.2	17.3 ± 8.9	0.2532
*Logistic EuroSCORE (%)	12.4 ± 9.5	11.1 ± 10.5	0.1077
*EuroSCORE II (%)	3.5 ± 4.0	2.6 ± 2.6	**0.0121**

BMI: Body mass index, BSA: Body surface area, ECG: Electrocardiography, NSR: Normal sinus rhythm, AF: Atrial fibrillation, LBBB: Left bundle branch block, NHYA: New York Heart Association, CCS: Canadian Cardiovascular Society, STS: Society of Thoracic Surgeons, SVO: Small-vessel occlusion, COPD: Chronic obstructive pulmonary disease, PAD: Peripheral artery disease, FVC: Forced vital capacity, FEV1: Forced expiratory volume in 1 second, MI: Myocardial infarction.
* It has been calculated for over 58 patients for the sutureless group and over 65 patients for the conventional group because 4 patients' data were missing for each group.

Table 2. Patients' perioperative parameters

	Sutureless	Conventional	p
Valve type (n, %)			
With stent	62 (100.0)	10 (14.5)	
Without stent		59 (85.5)	
Valve size (n, %)			**0.003**
19 mm		5 (7.0)	
S: 21 mm	28 (45.0)	24 (35.0)	
M: 23 mm	12 (19.5)	29 (42.0)	
L: 25 mm	16 (26)	9 (13.0)	
XL: 27 mm	6 (9.5)	2 (3.0)	
Mean valvular size	23.0	22.3	0.1952
Trademarks			
Sorin mitroflow		26	
Medtronic mosaic		17	
St. Jude Biocor/epic supra		5	
Edwards CE standard		3	
Medtronic Hancock 2		4	
Sorin freedom solo		10	
St. Jude Biocor/Epic		2	
Labcor porcine		1	
St. Jude Trifecta		1	
Sorin Perceval S	61		
Edwards İntuity	1		
*Cardiopulmonary bypass time (min)	87.5 ± 40.7	117.4 ± 66.3	**< 0.0001**
*Aortic cross-clamp time (min)	53.8 ± 34.2	79.2 ± 36.3	**< 0.0001**
Incision type			**< 0.0001**
Full median sternotomy (n, %)	40 (65.0)	65 (94.0)	
Mini-incision (n, %)	22 (35.0)	4 (6.0)	
*Urgent operation (n, %)	3 (5.0)	1 (1.5)	0.3459

*It has been calculated for over 58 patients for the sutureless group and over 65 patients for the conventional group because 4 patients' data were missing for each group.

types and marks, mean valve sizes, types of incisions, and comparison of ACC and CPB times.

Procedural Outcomes

Intubation, intensive care, and hospitalization times were found to be significant in conventional group (p1= 0.0153, p2= 0.0462, p3= 0.031, respectively). No significant difference was found in mortalities due to all causes and cardiac causes (Table 3) in the early period (< 30 days). More patients needed pacemaker support in the sutureless group postoperatively; however, the difference was insignificant (Figure 1). Peak and mean aortic valve gradient decreased significantly in both groups after surgery. Both groups showed similar hemodynamic results in the postoperative follow-up echocardiographic assessment (Figures 2, 3).

Midterm Results

No significant difference was found in mortality due to all causes (p1) and cardiac causes (p2) in the midterm period (> 30 days) (p1= 1.000, p2= 0.397). The overall survival rates in the sutureless valve group and conventional valve group were found to be 72.6% and 78.3%, respectively, (p= 0.253) when all-cause deaths were taken into account and Kaplan-Meier survival analysis was performed (Figure 4).

Table 3. Early postoperative parameters

	Sutureless	Conventional	p
*Intubation time (hour)	15.2 ± 10.6	12.5 ± 10.8	**0.0153**
*First day drainage (mL)	523 ± 431	496 ± 314	0.7454
*Total drainage (mL)	954 ± 906	804 ± 772	0.5487
*Intensive care unit time (hour)	121.9 ± 215.2	75.2 ± 119.2	**0.0462**
*Fresh frozen plasma transfusion (unit)	2.2 ± 1.7	2.2 ± 1.9	0.795
*Erythrocyte transfusion (unit)	2.0 ± 1.9	2.7 ± 2.5	0.100
*Fresh blood transfusion (unit)	0.5 ± 0.8	0.5 ± 0.7	0.687
*Platelet transfusion (unit)	1.8 ± 11.3	4.7 ± 23.2	0.278
Hospitalization (days)	14.3 ± 10.9	11.9 ± 9.7	**0.031**
Early-term mortality (all reasons) (n, %)	5 (8.0)	2 (2.9)	0.255
Early-term mortality (cardiac) (n, %)	1 (1.6)	1 (1.4)	1
Midterm mortality (all reasons) (n, %)	11 (19.3)	13 (19.4)	1
Midterm mortality (cardiac) (n, %)	4 (7.0)	9 (13.4)	0.379
Cumulative follow-up time (patient-years)	159.0	99.4	
Mean follow-up time (month)	19.5 ± 15.7 (17.27)	28.0 ± 21.0 (19.55)	0.042

* It has been calculated for over 58 patients for the sutureless group and over 65 patients for the conventional group because 4 patients' data were missing for each group.

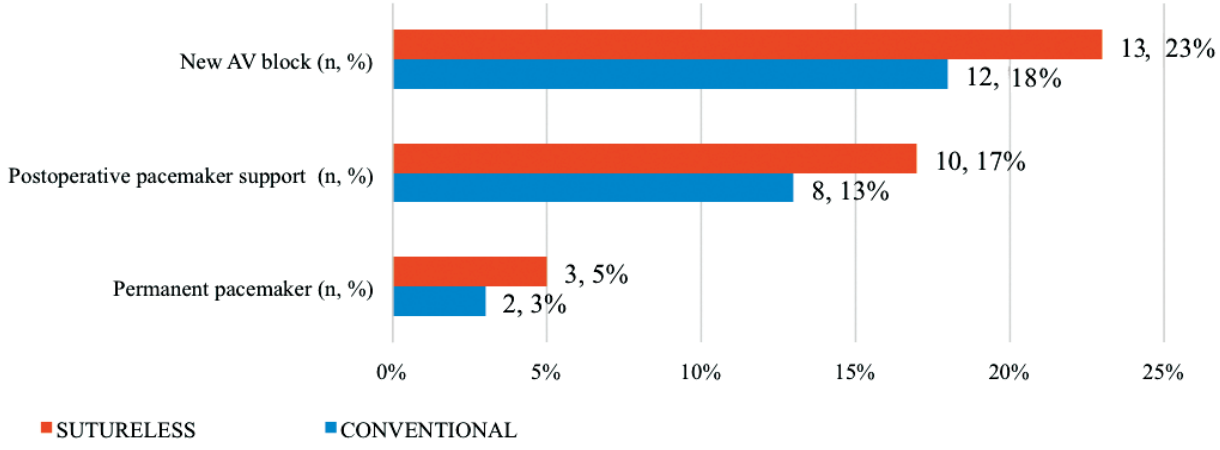


Figure 1. Postoperative rhythm change and pacemaker support.

DISCUSSION

Our study compares sutureless valve replacement for high-risk patients with conventional valve replacement for relatively lower-risk patients. Literature says mean ACC and CPB times for patients with sutureless AVR were significantly shorter than the patients with conventional AVRs. Previous studies showed that the duration of surgery, ACC, and CPB times were independent risk factors for mortality and morbidity in open heart surgery[4]. Ranucci et al. reported that ACC time was an independent predictor of cardiovascular morbidity, and there was a 1.4% increase in relative risk in morbidity for every extra 1-minute cross-clamp time[5]. This relationship has been demonstrated recently, even in AVR surgery, which has shorter ACC times compared to other cardiac surgery operations[5]. Shrestha et al. have found CPB time as 58.7-75.3 minutes, ACC time 30.1-50.3 minutes in the sutureless valve group; Hurley et al. in their meta-analysis have found CPB time of 64.9 minutes, ACC time 39.8 minutes in sutureless prostheses[6,7].

In our study, CPB and ACC times are 87.5 (minimum: 28 minutes, maximum: 216 minutes) and 53.8 (minimum: 15 minutes, maximum: 175 minutes) in SU-AVR group, respectively, and 117.4 (minimum: 48 minutes, maximum: 540 minutes)

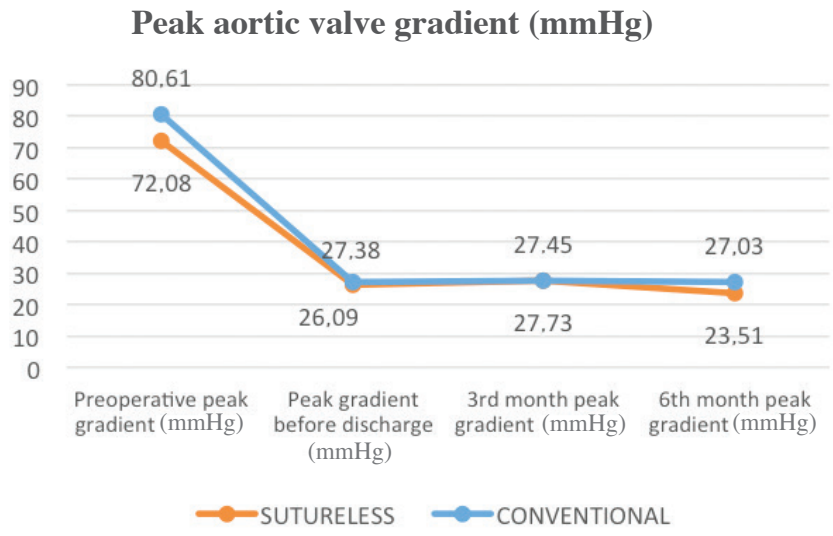


Figure 2. Comparison of peak gradient with preoperative, postoperative, and postoperative third and

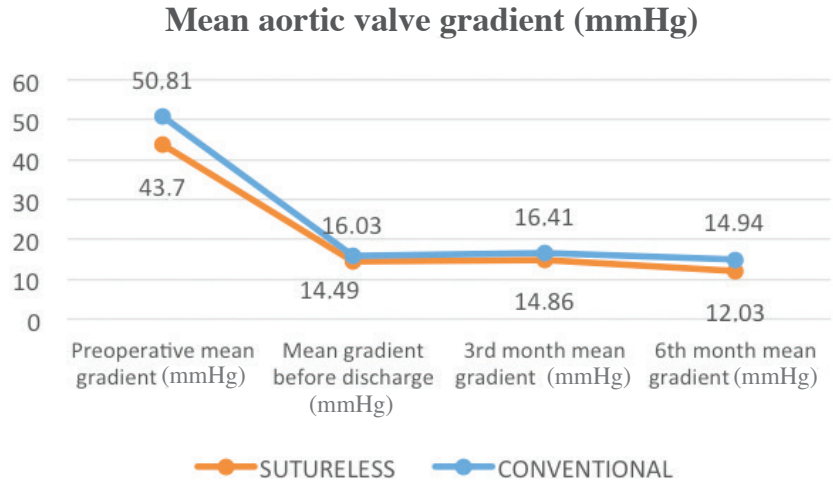
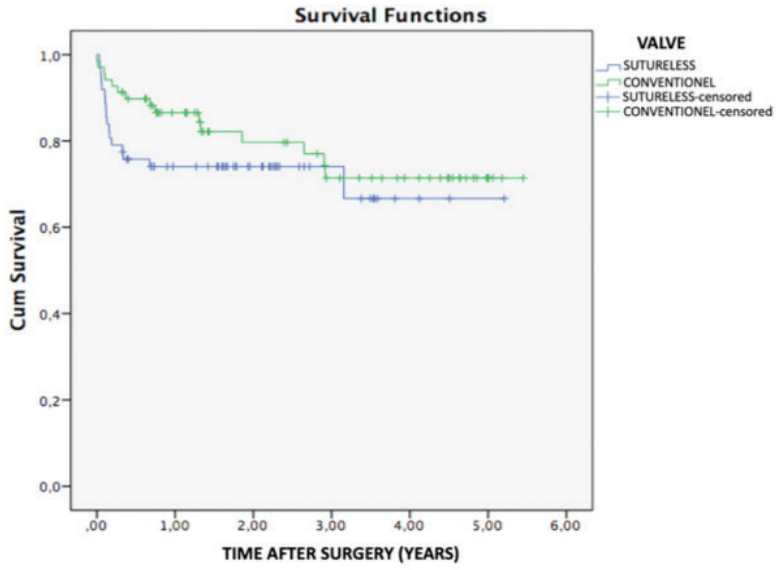


Figure 3. Comparison of the mean gradient with preoperative, postoperative, and third and sixth postoperative months.

and 79.2 (minimum: 30 minutes, maximum: 226 minutes) in C-AVR group, respectively. The difference will be significant when the groups are compared in terms of both parameters. The long operation times in our study for a sutureless group as compared to other studies might depend on two reasons. The first one is different surgeons operate the patients (more than five). Each surgeon has his/her learning curve. When we examine it chronologically, it is seen that the ACC time decreases significantly with the experience. The second reason is that the minimally invasive rate is 35% higher in the sutureless group.

In 2015, a multicenter study published by François Laborde et al. had showed that median sternotomy approach was used in 66.7% of (439 of 658) patients who underwent Perceval sutureless AVR[8]. A minimally invasive surgical approach was use for the remaining 219 patients (33.3%) (216 ministernotomy and 3 right anterior minithoracotomy). Forty (65%) patients with sutureless AVR were performed with median sternotomy, 22 (35%) with the minimally invasive intervention (16 ministernotomy and 6 right anterior minithoracotomy). For a conventional group, 65 (93%) median sternotomy, 4 (6%) minimal invasive approach were performed. A significant difference



Case Processing Summary

VALVE	Total N	N of Events	Censored	
			N	Percent
SUTURELESS	62	17	45	72,6%
CONVENTIONAL	69	15	54	78,3%
Overall	131	32	99	75,6%

Figure 4. Kaplan-Meier survival curve and analysis percentage (all-cause mortality).

was found when the surgical approach was compared in the two groups. Thus, it can be said that the use of a sutureless aortic valve facilitates minimally invasive intervention.

The average gradients (regardless of their size) of conventional aortic prostheses are more than those of sutureless prostheses[9]. In our study, postoperative first echocardiographic results show peak gradient as 26.0 ± 9.1 and mean gradient as 14.4 ± 5.6 that for sutureless group; for conventional group, peak gradient is 27.3 ± 10.7 and mean gradient is 16.0 ± 7.3. No statistically significant difference was found in both groups in terms of peak gradient and mean gradient. Another surprising fact about sutureless valves is that these gradients are conserved over time, making them even better than the first implantation time after a few years[10]. In parallel with this information, it was observed that the peak gradient in the sutureless group decreased to 23.5 ± 8.1 in the sixth month as per the results of control echocardiography; the mean gradient was 12.0 ± 4.6.

Unlike sutureless valves, conventional aortic valve prostheses are fixed using multiple sutures in the aortic annulus. In conclusion, it has been stated in some studies that periventricular leukomalacia (PVL) is very rare, with low rates between 0.1% and 5%[11]. In our study, in the postoperative first control echocardiography, more than mild PVL ratios were compatible with the literature, 3.2% in the sutureless group, and 2.9% in the conventional group[12,13].

Although the pacemaker implantation rates after sutureless AVR are found to be slightly higher than expected after standard AVR in the literature, the incidence of permanent pacemaker implantation is in a wide range (2%-10% range)[13,14]. The main reason for this is lack of common pacemaker implantation strategy in case of postoperative block development. In our study, the rates of blocking in the postoperative cardiac rhythm in the SU-AVR and C-AVR groups were 23% and 18%, respectively; the rates of admission to the postoperative pacemaker support were 17% and 13%, respectively. The rates of transition to permanent pacemaker were found as 5% and 3%, respectively. There was no significant difference between the two groups. These results were seen to be parallel with other studies[15]. The manufacturer recommended balloon dilation at 4 atm pressures during sutureless valve implantation. This relatively high pressure was blamed for higher pacemaker rates for sutureless valves. Nowadays, lower-pressure balloon dilation is recommended by many groups[14]. We started with higher pressures at the beginning of our series, but lower pressures

were used afterword. In the Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry study that evaluated the early results of 3343 patients operated between 2007 and 2017, the average overall pacemaker implantation rate was found to be 10.4%[15]. The pacemaker implantation rate has been shown to significantly decrease from 17.2% to 5.4% throughout the study, and it has been suggested that the main reason may be the "learning curve effect" in terms of procedural implantation steps and mainly sizing.

In our study, mean intubation time (p1), mean intensive care unit time (p2), and mean hospitalization time (p3) were found to be statistically significantly longer with the sutureless group as compared to the conventional group, different from the other studies in literature[16]. It can be related to the higher EuroSCORE values of the sutureless valve group. Besides, when interpreting this situation, which is in contrast with the literature, we have found that patients with high surgical frailty scores are directed to sutureless valve operation at the time of evaluation of the preoperative cardiology-cardiovascular surgery council.

Hospital stay in both groups was slightly longer than current literature[15,17]. There was no inpatient cardiac rehabilitation and care clinic to serve postoperative patients in our hospital. Another reason for the extended hospital stay in the postoperative period was the hospital where the study took place was a reference hospital that served throughout the country and accepted a large number of patients from outside the city

It has been emphasized in many studies that SU-AVR does not make a difference in terms of early mortality compared to C-AVR[17,18]. In our study, although early mortality due to all causes was not statistically significant, it was found higher in the sutureless group (8.0%, n= 5) compared to the conventional group (2.9%, n= 2). However, both groups showed similar results in mortality due to cardiac causes (sutureless group 1.6%, n= 1; conventional group 1.4%, n= 1). Both groups also showed similar results in midterm mortality due to all causes. However, midterm mortality due to cardiac causes in C-AVR group was shown to be almost two times higher than SU-AVR. When we make a general evaluation considering all mortality rates, unlike other studies, we can easily say that the sutureless aortic valve has a significant positive effect in decreasing the expected mortality in the early and midterm periods.

In our study, the cumulative patient follows for the sutureless group about survival was 99.4 patient-years, mean following time was 19.5 ± 15.7 (19.5) months, and for conventional group 159.0 patient-years, mean following time 28.0 ± 21.0 (17.2) months. Overall survival rates in the sutureless and conventional groups were found to be 72.6% and 78.3%, respectively, when evaluated by Kaplan-Meier survival analysis. There was no statistically significant difference between the two groups. These rates were found to be similar with the current studies[12].

LIMITATIONS

Lack of generalizability due to its reliance on data from a single institution and a limited number of cases are the major limitations of our study. Another shortcoming is that the study is a retrospective non-randomized clinical study; the data of patients included in the study are not available for analysis. The short follow-up time of patients and the difference create question marks in terms of accuracy, especially in the statistical comparison of long-term results. Although different surgical teams and surgeons of the same hospital have performed operations, the use of different valves in the C-AVR group causes the findings in some parameters to be on a large scale.

CONCLUSION

Sutureless aortic valves appear as a promising alternative to conventional valves, especially in elderly and high-risk patients with comorbid diseases. However, we do not have enough information on the durability and long-term complications of these valves because of the shorter follow-up times. More randomized clinical trials with large sample size and long-term follow-up are required for routine use of these valves in a younger and lower-risk patient group.

Ethics Committee Approval: The study was approved by the Department of Ethics of Maltepe University (No: 2016/900/09, Date: 15/04/2016).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept/Design - FÖ, TA, HMA; Analysis/Interpretation - FÖ, TA; Data Collection - FÖ, DÇ, MŞ; Writing - FÖ, OT; Critical Revision -TA, VB; Final Approval - FÖ; Statistical Analysis - FÖ, TA; Overall Responsibility - FÖ, TA, HMA.

Conflict of Interest: The authors declared that there was no conflict of interest during the preparation and publication of this article.

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