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Original Article

Erhan Hafız[1], Ozgur Altinbas[2], Isik Betil Kutlu[1], Mehmet Adnan Celkan[1]

[1]Gaziantep University, Faculty of Medicine, Department of Cardiovascular Surgery, Gaziantep, Türkiye
[2]Gaziantep University, Vocational School of Health Services, Operation Room Services Gaziantep, Türkiye

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Corresponding Author: Ozgur Altinbas
Gaziantep University, Vocational School of Health Services, Operation Room Services Gaziantep, Türkiye
Email: ozgur_altinbas@yahoo.com

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Comparison of clinical outcomes of sutureless and conventional mechanical aortic valves

Abstract

Aim: Aortic stenosis is a prevalent valvular disease characterized with outflow obstruction of left ventricle especially in patients with advanced ages. Definitive treatment of this disorder is valve replacement and done via different kinds of prosthetic valves. Herein we aimed to compare the clinical outcomes of the individuals underwent aortic valve replacement by using sutureless or conventional mechanical valve.
Material and Methods: Between 2020-2023, totally 102 patients underwent aortic valve replacement due to severe aortic stenosis were involved in the study. Patients were seperated into two groups according to the valve prothesis used in operations, sutureless valve group (n=50) and conventional mechanical valve group (n=52).
Results: The mean duration of cardiopulmonary bypass and side clamp and were significantly decreased in the sutureless valve group than conventional one (52.6±32.2 vs. 77.4±35.3 minutes and 86.4±18.5 vs. 121.8±13.45 minutes, p<.001). Duration of mechanical ventilation, intensive care unit (ICU) stay and hospitalization were also significantly lower in sutureless group.
Conclusion: Although patients operated by using sutureless valve are older, they have satisfactoried intra and postoperative outcomes. Therefore, aortic valve replacement operations can be performed reliably with sutureless valves in patients with advanced ages.

Keywords: Aortic valve, aortic valve replacement, mechanical valve, sutureless valve

INTRODUCTION

Aortic stenosis is a worldwide disease characterized with outflow obstruction to left ventricle (1). It may either congenital or acquired. Bicuspid aorta is the most common cause of aortic stenosis related to congenitally abnormal valve in patients under 70 years in developed countries whereas rheumatic valve rheumatic valve disease plays a main role in the etiology of the disease in developing countries (2). Incidence of the aortic stenosis increases with the age and can be mortal in symptomatic patients if left untreated (3). Gold standard treatment option for severe and symptomatic aortic stenosis is a surgical procedure called aortic valve replacement (AVR) (4). AVR can be performed by using mechanical or bioprosthetic valves. Sutureless valves are recently introduced bioprosthetic valves and can be replaced with no more than three sutures within the aortic annulus (5). Herein we aimed to compare the intraoperative and postoperative clinical outcomes of the patients underwent AVR with conventional mechanical valve or sutureless valve.

MATERIAL AND METHODS

Between 2020 to 2023 totally 102 patients to whom replacement of aortic valve was performed due to severe aortic stenosis were involved in the study. Ethical committee approval was obtained from the institute (date: 02.08.2023, desicion no: 2023/234). A written informed consent was taken from all individuals and the study was designed according to Declaration of Helsinki.

Patients were seperated into two groups according to the valve type used in the operation. Group 1 was consisted of 50 patients operated by using sutureless valve and Group 2 was consisted of 52 patients operated by using conventional mechanical valve. Demographic characteristics of the patients, comorbidities, laboratory findings, electrocardiography and echocardiography records, intraoperative and postoperative data were obtained from the hospital system. Operative mortality was defined as postoperative deaths within thirty days.

All of the individuals had severe aortic stenosis without any additional valvular or coronary disease. According to the echocardiography results; aortic valve area under 0.6 cm^2, mean transvalvular gradient over 40 mmHg and peak aortic velocity over 4 m/sec were accepted as severe aortic stenosis (6). For the detection of any coronary artery disorders we performed oronary angiography to all patients. An additional CT angiography was planned for the patients who undergoing sutureless valve replacement to evaluate annular and sinotubular junction diameter, calcification of ascending aorta and annulus. Operations were performed via full sternotomy. Pregnants, patients <18 years of age, patients with any additional valve and/or coronary artery disease required surgery or having any cancer and re-do interventions were excluded to the study.

Statistical Analyses

Statistical analysis was performed by using SPSS version 17.0 software (SPSS Inc, Chicago, IL). Methods of descriptive statistics were used. Comparison of normal distribution of quantitive data and comparison of abnormal distribution of quantitive data were performed by using Student's t-test and Mann-Whitney U test, respectively. Data of the groups with normal distribution and data of the groups without normal distribution was calculated by Paired sample t-test and Wilcoxon sign test, respectively. Pearson's chi-square tests and Fischer's exact test were used for qualitative data. P values less than 0.05 were accepted significant.

RESULTS

The patients involved in Group 1 are statistically significantly older than Group 2 (Table 1).

There were no statistically significantly differences in the evaluation of preoperative echocardiography in terms of mean transvalvular gradient, aortic valve area, and peak aortic velocity.

Althuogh ejection fraction (EF) rates are lower in Group 1, it was not statistically significant. Preoperative laboratory measurements, existence of atrial fibrillation, comorbidities and ejection fraction rate of the groups were given in Table 2.

Duration of cross-clamp, cardiopulmonary bypass time and ICU stay were statistically significantly lower in Group 1. Intra and postoperative data of the groups were summarized in Table 3.

Three of the individuals in Group 1 and four of the individuals in Group 2 were reoperated in the operation day due to hemorrhage. Three of the patients were died due to permanent cerebrovascular disease and two of them were due to sepsis in Group 1. Causes of the deaths were same in Group 2; sepsis (n=2) and permanent cerebrovascular disease (n=2).

Table 1. Demographic data of the groups

	Group 1 (n=50)	Group 2 (n=52)	p value
Female n (%)	27 (54)	28 (53.84)	0.936
Male n (%)	23 (46)	24 (46.16)	0.915
Age (years)	76.46±5.47	66.34±6.43	0.015*

Table 2. Preoperative clinical and laboratory findings of the groups

	Group 1	Group 2	P
Hemoglobin (g/dL)	13.65±1.09	13.48±1.24	0.839
Urea (mg/dL)	13.25±4.54	14.25±3.32	0.261
Creatinine (mg/dL)	0.86±0.15	0.82±0.18	0.774
Alanine aminotransferase (IU/L)	22.6±10.31	23.6±10.34	0.551
Aspartat aminotransferase (IU/L)	21.54±8.57	22.36±7.79	0.571
Hypertension: n (%)	28 (56)	31 (59.6)	0.232
Diabetes mellitus: n (%)	9 (18)	8 (15.3)	0.842
Hyperlipidemia: n (%)	6 (12)	7 (13.4)	0.756
COPD: n, (%)	4 (8)	4 (7.6)	0.774
Atrial fibrillation: n, (%)	10 (20)	11 (21.1)	0.746
Ejection fraction (%)	47.28±4.53	49.20±7.48	0.061

COPD: chronic obstructive pulmonary disease

Table 3. Intraoperative and postoperative data of the groups

	Group 1	Group 2	P
Duration of cross clamp (min)	52±32.2	77±35.3	<.001*
Duration of CPB (min)	86.4±18.5	121.8±13.45	<.001*
Drainage (ml)	349±42	375±35	0.186
ICU stay (hour)	21.06±8.44	23.47±9.75	0.023*
Hospital stay (day)	3±1	6±1	<.01*

CPB: cardiopulmonary bypass, ICU: intensive care unit

DISCUSSION

Aortic valve stenosis is the most widespread valvular disease in western countries. Prevalence of the disease is 3% in individuals over 75 years of age. An increased incidence is present due to ageing of the community (7). Aortic valve stenosis leads to an obstruction in left ventricular outflow tract which causes syncope, angina, congestive heart failure and left ventricular hypertrophy. Annual mortality reaches up to 30% in symptomatic patients if left untreated (8). Gold standard tool for diagnosis of aortic valve stenosis is echocardiography. It allows evaluating of the valvular anatomy, orifice area and the severity of the calcification on valvular surface. Left ventricular ejection fraction detected in echocardiography gives clues about probable adverse events such as mortality (9).

Medical treatment has not advanced effect on disease progression in aortic valve stenosis. Primary aim in medical treatment is to focus on additional cardiac comorbidities such as coronary artery disease, hypertension, atrial fibrillation and other dysrhythmias and left ventricular dysfunction. (10,11). Anticoagulation therapy in suitable patients with atrial fibrillation is essential to prevent undesired embolic events (12).

Gold standard treatment for severe aortic valve stenosis is the surgical intervention. Main surgical treatment modalities include aortic valvuloplasty with balloon (BAV), transcatheter aortic valve implantation by transcatheter access (TAVI) and traditional AVR (13).

BAV is indicated in subjects with severe and symptomatic aortic stenosis who are inoperable because of comorbidities and clinical status. Due to failure to improve long term survey and early restenosis rates it is considered as a palliative treatment for patients with high risk who are not suitable for open surgery (14). BAV is performed as a bridge to TAVI or AVR or for patients with severe and symtomatic aortic valve stenosis who need to be an urgent non-cardiac operation. In a study designed by Wendt et al. (15), high-risk patients were defined as Society of Thoracic Surgeons (STS) Score >10% and/or European System for Cardiac Operative Risk Evaluation (EUROSCORE) >15% with severe aortic stenosis.

Severe comorbidities and advanced age are big challenges in patients with aortic valve stenosis and over 30% of the patients defined as high risk who are not suitable for major surgical intervention. TAVI is a new method which can be performed in high-risk patients unfit for surgery (16). Currently, TAVI is recommended in patients with severe aortic valve stenosis and have symptoms and expected postprocedural survival is >12 months. Nevertheless, low risk patients, bicuspid structered aortic valve, pure native aortic regurgitation, unsuccessful surgical bioprosthesis, severe asyptomatic aortic stenosis and moderate aortic stenosis with congestive heart failure are accepted as expanded TAVI indications (17).

AVR can be performed by using mechanical or bioprosthetic valves. Each of them have benefits and risks. (18). Life expectancy, anticoagulant requirement, INR monitoring capacity, lifestyle, patients' preference, risk of reoperation and/or bleeding must be considered in choosing the suitable valve. However patient age is the most determining factor in clinical practice (19). Both American Heart Association/American College of Cardiology (AHA/ACC) and/or European Society of Cardiology (ESC) recommended mechanical valve for AVR under age of 60 years. ESC states that bioprosthetic valve should be considered for AVR in patients over 65 years whereas AHA/ACC states that bioprostehetic valve should be preffered for AVR in patients over 70 years (20). All of the patients to whom sutureless valve used were over 70 years in our study.

Suturelss aortic valves are kind of bioprosthetic, paricardial valves which anchor within annulus of the aorta with three sutures. Currently there are three kinds of suturelss valve prosthesis; 3F Enable (Medtronic, Minneapolis, USA), Intuity Elite (Edward Lifesciences, Irvine, USA) and Perceval S (Sorin, Saluggia, Italy) (7). We used Perceval S because it is the unique trademark refunded.

There are various advantages of sutureless valves in terms of duration of cross clamp, cardiopulmonary bypass, ICU and hospital stay over mechanical valves. Extended duration of cardiopulmonary bypass and cross clamp were associated with mortality. Moreover, cross clamp time was detected to be an independent predictor of cardiovascular morbidity (21). In a meta-analysis of 12 studies about sutureless aortic valves, mean cross clamp time was 45 minutes (22-70 min.) and mean cardiopulmonary bypass time was 73 minutes (46-111 min.) (22). Duration of cardiopulmonary bypass and cross clamp were within the limits mentioned in literature in our study. In a study designed by Ozturk et al. (3), both duration of cardiopulmonary

bypass and cross clamp were found to be significantly decreased in sutureless valve group. Similarly, Hanedan et al. (23) declared the superiority of sutureless valves in terms of same parameters over mechanical valves. In a study enrolled 164 patients opertaed by using sutureless or mechanical valves due to aortic stenosis, duration of cardiopulmonary bypass and cross clamp were found significantly lower in sutureless group (24). Shrestha et al. (25) declared similar results in a total of 120 patients. Our results revealed significantly shortened cross clamp and cardiopulmonary bypass data parallel with the literature.

Lesser ICU and hospital stay are available in literature related to sutureless valves rather than mechanical ones. ICU and hospital stays were found shorter in sutureless valve group compared with mechanical valve group in a workout conducted by Pollari and colleagues (24). Hanedan et al.(23) emphasized that sutureless valves have more advantages on ICU and hospital stays when compared with mechanical valves in aortic valve surgery. Decreased ICU and hospital stays were also mentioned in a study related to suturelss valves designed by Gode et al. (26). Santarpino et al. (27) revelaed that shortening the operation time has positive impacts on postoperative improved outcomes such as ICU and hospital stays. Our results were compatible with the literature in terms of those parameters.

Sutureless aortic valve replacement can also be performed via right anterior thoracotomy. Severeal studies were designed and empasized the success of the procedure in the literature. Durdu et al. (28) used this technique in patients with severe aortic stenosis and bicuspid aortic valve without in hospital mortality. Similarly, Solinas et al. (29) performed right anterior thoracotomy while replacing the suturless aortic valve over 1049 patients and declared the safety and feasibility of the method.

Single centered and retrospective natures of our study can be defined as the limitations.

In our opinion all of the four parameters statistically significantly lower in sutureless valve group are associated with economical and psychosocial positive outcomes. Extended operation time causes longer ICU and hospital stays which means economic burden both to the patients and governments. While the discharge period longers, individuals can not get away from patient psychology, therefore recovery period does not function appropriately.

CONCLUSION

In conclusion AVR can be achieved with shortened cross clamp and cardiopulmonary bypass times via sutureless valves. In addition, decreased duration of ICU and hospital stays are available with sutureless valves. Long term studies with multi center involvement is required in the future.

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