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Early postoperative hemodynamic performances of stented versus stentless aortic xenografts in aortic valve replacement in elderly patients: a comparative study

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Abstract. – BACKGROUND AND AIM: Surgical valve replacement is the most commonly performed for aortic stenosis. Randomized trials comparing stentless to stented bioprostheses for aortic valve replacement in elderly are scarce. The aim of our study was comparing and evaluating the early hemodynamic performances of Hancock™ stented and FreeStyle™ stentless xenograft aortic valves in aortic valve replacement in elderly patients.

PATIENTS AND METHODS: The study involved 40 patients (27 females and 13 males) older than 75 years old. The study was done during the postoperative period. Aortic valve replacements of stented and stentless xenografts were performed to the patients in Group I and Group II, respectively. Investigations for the echocardiographic results were completed on the postoperative 8-10th days. Parameters for the evaluation of hemodynamics were peak pressure gradient, mean pressure gradient and effective orifice area. The parameters were calculated with Doppler echocardiography by using specific formulas.

RESULTS: Peak pressure gradients in patients with stented valves were significantly higher than in stentless valves [Stented valve group 32.45 ± 7.58 vs Stentless valve group 21.50 ± 4.77 mmHg] ($p < 0.05$). Mean pressure gradients were found to be significantly higher in stented group compared with stented group [Stented valve group 11.050 ± 3.2521 vs Stentless valve group 19.350 ± 6.6036 mmHg] ($p < 0.05$). The effective orifice area index of implanted valve was significantly greater in the stentless group, as well [Stentless valve group 2.5050 ± 0.6022 vs Stented valve group 1.3050 ± 0.3316 cm^2] ($p < 0.05$).

CONCLUSIONS: In early postoperative period, effective orifice areas and pressure gradients were found higher in stentless valve group.

Key Words:
Surgical aortic valve replacement, Elderly patients, Stentless valve, Stented valve.

Introduction

Aortic valve stenosis (AVS) is the most common valvular heart disease in the world. The prevalence of moderate or severe aortic stenosis in patients ≥ 75 years old is 2.8%[1]. Aortic stenosis is a progressive condition and after the onset of heart failure, survival is < 2 years without valve replacement[2]. Prognosis of the disease worsens with development of typical symptoms such as chest pain, syncope and dyspnea, or a decline in the left ventricular ejection fraction (LVEF)[3]. Approximately 50% of patients with severe aortic stenosis are refereed for cardiothoracic surgery and nearly 40% undergo aortic valve replacement. Reasons for not undergoing aortic valve replacement included high perioperative risk, age, being asymptomatic, and refusals[1]. Aortic valve replacement is currently used in patients with severe aortic stenosis. Homografts for aortic valve replacement (AVR) were the first biologic stentless prostheses used in clinical practice in the 1960s. Tissue valves are used mostly in elderly people due to low risk of calcification compared with young people and requirement of anticoagulation therapy[4]. The most important complication of AVS is left ventricular hypertrophy and the postoperative regression of hypertrophy is an important factor for survival[3,5]. Incomplete regression of LV hypertrophy has been shown to significantly reduce 10-year survival[4,6].

Both stentless and stented valves are used in the valve replacement surgery. Porcine aortic valves or stented pericardial tissue facilitated the implantation technique. However, these valves limited orifice area and enhanced stress at the attachment point which led the earlier primary tis-

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sue failure. In the early 1990s, the use of bioprostheses increased due to improved durability and low prosthetic mismatches[7].

Stentless valves compered to stented ones have larger external orifice area which improves regression of left ventricular hypertrophy better. On the contrary, cross clamp times and by-pass times are longer[8]. The net results of ventricular function after in both types of surgeries are still controversial and have been founded to be different in several reports[5]. Primary tissue failure is a serious complication after biological valve implantation. Xenogenic stentless aortic valves withdraw the stress at the stent sites and this provides better durability in theory. According to the various studies, better hemodynamic performance and earlier LV mass regression were thought to be the reason for the improvement of survival after stentless AVR in the comparison with stented AVR[7].

The aim of our randomized study was to compare stentless valves (Freestyle) with stented valves (Hancock) in terms of peak, mean pressure gradients and effective orifice areas.

Patients and Methods

This prospective, randomized, non-blinded study included 40 patients (27 female, 13 male) older than 75 years. Eligible patients were those with aortic valve stenosis and/or aortic valve regurgitation scheduled for aortic valve replacement surgery. All patients were randomly divided into 2 groups: patients (n=20) underwent stented (Hancock™) aortic valve replacement surgery and those (n=20) underwent stentless (FreeStyle™) aortic valve replacement surgery. Patients' demographics are shown in Table I. Preoperatively, transthoracic echocardiography and coronary angiography were performed to all patients. Intraoperatively, the annulus size of aorta was measured and patients with annulus size greater than 2.5 cm were excluded.

All patients were digitalized preoperatively and postoperative 3 months; anticoagulation treatment had been applied according to the results of Quick prothrombin time tests and INR levels. In addition, life-long prophylactic endocarditis treatment was provided.

The study was done during the postoperative in-patient period. Investigations for the echocardiographic results were completed on the postoperative 8-10th days. CK, CK-MB, AST, ALT, LDH levels were evaluated in the postoperative 3rd and 6th hours and in the postoperative 1st, 2nd and 3rd days. The differences between the enzyme levels of two groups were not found significant ($p > 0.05$). Moreover, the extubation time of the groups was close to each other. When groups were investigated with the transthoracic echocardiography for the aortic regurgitation, no significant regurgitation was demonstrated.

Valves and Surgical Method

In valve replacement, Stentless aortic xenografts are similar with homografts in surgical manner. On the other hand, the replacement of stented xenografts is similar with that of mechanical valves.

After opening the pericardium by median sternotomy cardiopulmonary bypass was provided via ascending aorta cannulation. Venous cannulation was placed through superior and inferior vena cava. The vent was fixed to the left ventricle, the patient got cooled down to 30°C and total bypass was provided. The front view of sinotubular junction was obtained between aorta and pulmonary artery. Aortatomy was performed transversely 2-5 mm superior to sinotubular junction by placing

Table I. Patient demographics and operative data.

	Stentless valve (n = 20)	Stented valve (n = 20)
Female (%)	13 (65)	14 (70)
Age, years (SD)	79.85 (2.85)	80.10 (3.61)
NHYA score (SD)	3.05 (0.76)	3.10 (0.72)
Cross clamp times, min (SD)	81.7 (16.76)	53 (8.7)
By-pass times, min (SD)	106.15 (24)	68.2 (8.82)
EOAI, cm^2 (SD)	2.5 (0.6)	1.3 (0.33)
LVEF grades (SD)	1.65 (0.81)	1.85 (0.75)

(NHYA score = The New York Heart Association Functional Classification for Congestive Heart Failure, EOA = Effective orifice area index, LVEF grades = Left ventricle ejection fraction grades).

cross-clamp. The cut was done between the diameters of 5-10 mm. Therefore, the aorta separated into 2-3 transections and both of the coronary ostia became easy to visualize. Bretschneider solution which is used along with crystalloid cardioplegia for myocardium protection was administered to the coronary ostia from the root of the aorta. Cardioplegia was taken back from the right atrium before it joined to the systemic circulation. Then, the aortic valve was resected and the maximal valve area was achieved by decalcification process. Permanent Teflon supported sutures were placed to the aorta for retraction.

First suture was placed at the right coronary artery, second one was placed at the middle of non-coronary cusp and third one was placed for retraction of the other part of the aorta which was cut through its left side. After the suitable valve was chosen, annulus was surrounded by 2.0 ethibond sutures by suturing the base of every cusps with in number of 5-6. The valve sutures were placed to the sections surrounded by Dacron patches in the Xenograft. Xenograft was fixed carefully to the annulus by providing an equal level between the connected coronaries and native coronaries. Sutures were tied and cut. Xenograft connected coronaries were cut to be in U shape and suitable with native coronary ostia. The commissures of the Xenografts were fixed to the wall of aorta by using continuous 4.0 prolene sutures starting from right to left. Suture line was extended through non-coronary sinus to the part of the transected native aorta. Then, on the left side, the two walls were fixed each other by suturing with 4.0 prolene suture at the left subcoronary level. Binding of the sutures were performed at the meeting point.

Firstly, the part of the aorta where the transverse incision was performed was closed and then the air in the aorta and left ventricle was extracted.

On the other hand, in the stented Xenograft replacement, as in the mechanical valve replacement, annulus was passed with Teflon supported 2.0 ethibond suture. The sutures were slipped on the valve ring in traditional manner, and the valve was fixed in the aortic position. The aorta which had an oblique incision was closed. After the extraction of the air in the heart, the bypass was ended and the other surgical procedures were provided.

Doppler Echocardiography and Measurements

The method for the evaluation of different hemodynamic parameters measured with Doppler-echocardiography was suitable for the protocol created by American FDA (Food and Drug Administration)[9]. Echocardiographic views (Apical 2-4 chambers by placing sample volume 0.5-1 cm under the aortic valve) with 2D cineloops, M-Mode and color Doppler were recorded by video-tabe (Panasonic D-750, Secaucus, NJ, USA). The echocardiography devices used on all patients were Hewlett-Packard 1000 (Palo Alto, CA, USA).

Systolic flow velocity in left ventricle outflow tract (VLVOT) was measured as meter/second (m/sc). Continuous Doppler records were obtained blindly with Pedoff probe in apical, left parasternal and suprasternal, right parasternal and underneath the xphoid process positions. Maximal systolic velocity was assessed. Maximal systolic velocity of the aortic valve (V_{max}) was measured as m/sc. Consecutive three cardiac cycles in sinus rhythm were averaged for all measurement results.

The parameters were following: (1) Peak pressure gradient was calculated with simplified Bernoulli equation, $4\times(V_{max})^2$ formula[10-12]. (2) Mean pressure gradient was calculated automatically with echocardiography device from the highest systolic trans-prosthetic flow spectrum[13]. (3) Effective orifice area (EOA) was calculated with continuity equation and $\pi r^2 \times$ VLOT/max formula[14-16].

The areas are calculated with πr^2 formula. The radius of left ventricle outflow tract is measured independently from the left parasternal long axis visualization.

Statistical Analysis

For statistical analyses, Wilcoxon two-sample test was used. Results were shown as mean ± standard deviation. $p < 0.05$ was considered statistically significant.

Results

Forty patients were randomized into 2 groups, either stentless or stented aortic valve replacement. Mean age was 79.98 ± 3.17 and 68% of patients were female. While examining patients with transthoracic echocardiogram, none of patients showed clinically significant aortic regurgitation. Results were shown as mean ± standard deviation. $p < 0.05$ was considered statistically significant.

Table II. Preoperative cardiovascular pathologies.

	Total number (%)	Stented valve	Stentless valve
Senile degeneration	33 (82.5%)	16 (80%)	17 (85%)
Rheumatic fever	2 (5%)	2 (10%)	0 (0%)
Congenital pathology	2 (5%)	1 (5%)	1 (5%)
Myxomatous degeneration	1 (2.5%)	1 (5%)	0 (0%)
Prosthetic degeneration	1 (2.5%)	0 (0%)	1 (0%)
Endocarditis	1 (2.5%)	0 (0%)	1 (5%)

In both groups, 82.5% of patients who underwent aortic valve replacement surgery had senile degeneration. Preoperative patient selection showed in Table II.

Peak pressure gradients in patients with stented valves (Freestyle) were significantly higher than in stentless valves [32.45 ± 7.58 vs 21.50 ± 4.77 mmHg] ($p < 0.05$) (Figure 1).

Mean pressure gradients were found to be significantly higher in stented group compared with stented group [Stented valve group 11.050 ± 3.2521 vs Stentless valve group 19.350 ± 6.6036 mHg] ($p < 0.05$) (Figure 2).

Cross clamp times (81.7 ± 16.7618 vs 53 ± 8.8674 min) and cardiopulmonary by-pass times (106.15 ± 24 vs 68.20 ± 8.8294 min) were found to be significantly longer in stentless valve group ($p < 0.05$). Additionally, the effective orifice area index of implanted valve was significantly greater in the stentless group (Stentless valve group 2.5050 ± 0.6022 vs Stented valve group 1.3050 ± 0.3316 cm^2). Intraoperative statistics are shown in Table I.

Discussion

Stentless xenografts have been preferred in order to maximize the effective orifice area, suggesting a better LV mass regression and survival. In the study of Borger et al[17], patients with stentless bioprostheses showed better hemodynamical outcomes than stented group during the midterm follow-up. Additionally, it must be kept in mind that patient-prosthesis mismatch could potentially impair the regression of LV hypertrophy despite the effective replacement. However, the clinical impact of this issue is still arguable.

Stentless xenografts have been favored because of their advanced hemodynamical outcomes sug-

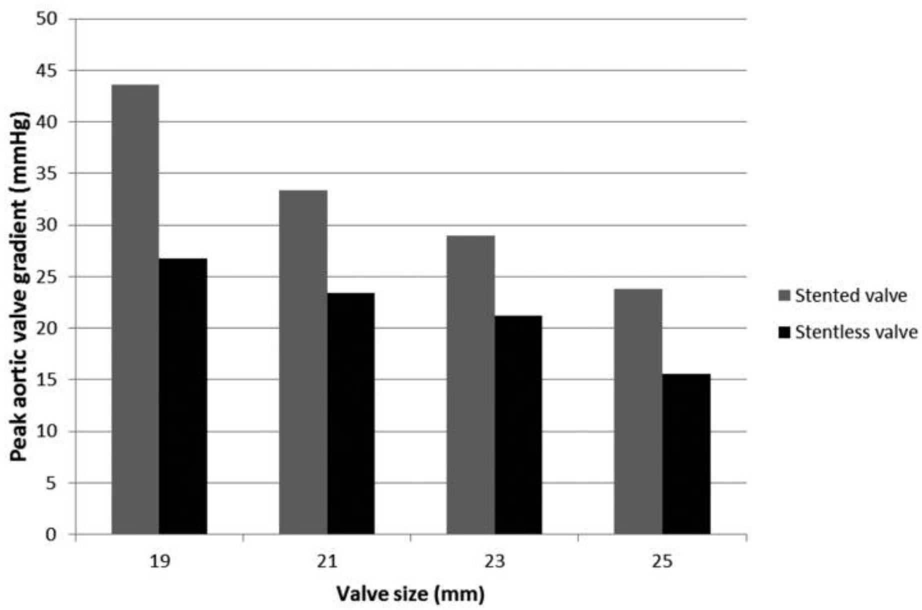

Figure 1. Peak aortic valve gradients of stented versus stentless valves.

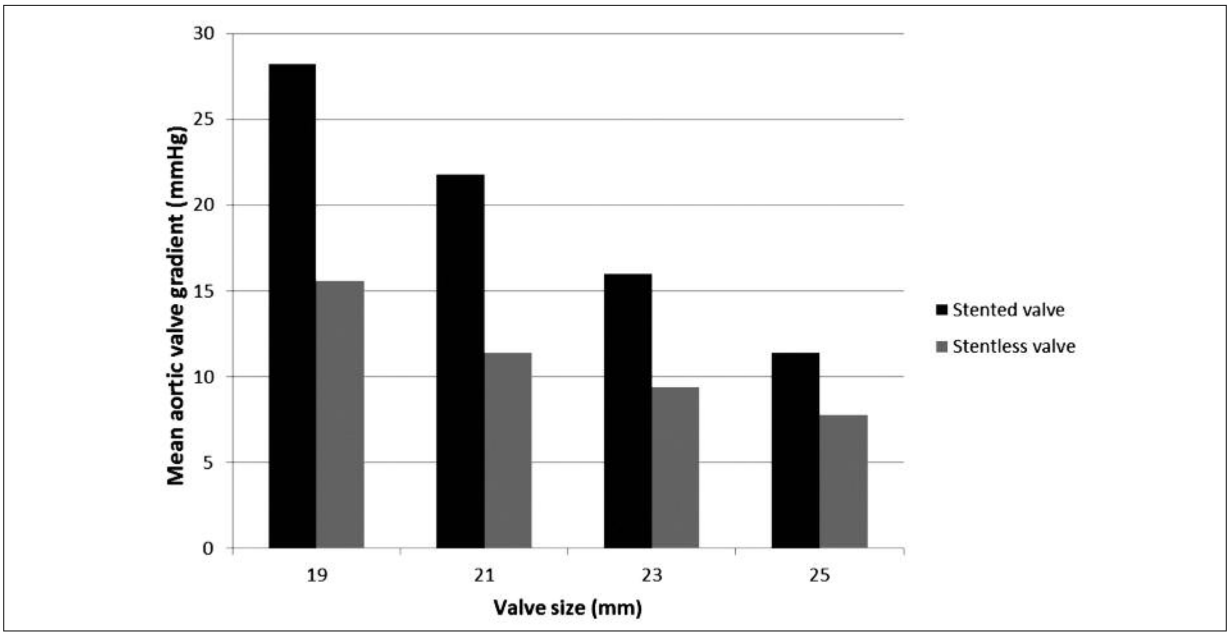

Figure 2. Comparison of mean aortic valve gradients in groups.

gesting a better LV mass regression and survival due to their larger effective orifice areas. Borger et al[17] have shown, Midterm follow-up in a large number of patients reveals that stentless bioprostheses are hemodynamically superior to stented valves. Moreover, a lot of interest has been addressed to the concept of patient-prosthesis mismatch as a factor that could potentially jeopardize the regression of LV hypertrophy despite effective aortic valve replacement[18]. However, the clinical impact of this issue is still controversial.

Peak pressure gradient (PG) parameter is one of the most used parameters for the evaluation of heart valve function. The validity of the Bernoulli equation, which is used for calculation of peak pressure gradient in Doppler echocardiography, is proved by several researches[11,12]. Difference between the calculated PG values in each group was found statistically significant ($p < 0.05$).

Mean pressure gradient (MG) parameter is more confident than PG parameter and had better correlation with invasive hemodynamic researches ($p < 0.05$)[12,13]. In our study this parameter was found significantly lower in stentless xenografts than in stented xenografts.

We have demonstrated that implantation of stentless valve results in significantly reduced aortic valve gradients.

Both peak and mean pressure gradient values in Jin et al review[19] about stented and stentless xenografts correlated with those in our study and these values were found significantly lower in stentless aortic valve group. Additionally, Dunning et al[5] also showed the same correlation in their randomized controlled study.

In early echocardiographic evaluations of bioprostheses, Chatel et al[20] have shown significantly lower peak and mean pressure gradients in stentless aortic valves than in stented aortic valves (< 0.05).

Peak and mean pressure gradients in the Kon et al report[8] were lower than the gradients in ours work whereas the effective orifice areas were found higher. However, surgical technique used by Kon et al was total root implantation and it was a different technique than that we used.

Effective orifice area (EOA) is one of the measurements used for evaluation of heart valve function with Doppler echocardiography. If it is calculated with continuity equation, it shows a meaningful correlation with EOA calculated with Gorlin formula in heart catheterization[14-16]. Effective orifice area was found significantly greater in stentless xenografts than in stented xenografts ($p < 0.05$). Likewise, in the report of Bove et al[21], the results of effective orifice area agreed with our findings.

Thompson et al[22] have shown a significantly lower effective orifice area in stented group than in stented aortic valve group ($p < 0.05$); calculations were done in early postoperative period likewise with our study.

Temporary pacemaker implantation was performed to all patients. One of the patients had 3-degree block after the Freestyle Xenograft implantation and was held to pacemaker. Therefore, a DDD pacemaker implantation was performed to the patient in the postoperative period.

A 78-year-old female patient had no differences between left ventricular and aortic pressure after Freestyle Xenograft implantation and had normal valve anatomies and normal gradients with the evaluation of transesophageal echocardiography (TEE) after cardiopulmonary bypass. However, on the postoperative 8th day, it was detected that she had a degree of 3-4 heart failure with a rupture of anterior leaflet. She had an emergent mitral bioprostheses implantation. At the intraoperative observation, it was noticed that the anterior leaflet had been fixed during the operation.

Another patient with Freestyle implantation, at the intraoperative period after the cardiopulmonary bypass, mean pressure gradient was found 50 mmHg. As a result of the importance of this pressure value, re-implantation of the valve was performed. The myocardium needed to be protected as the cross-clamp time was exceeded. The protection was provided by repeating the cardioplegic solution (Bretschneider) administration.

In the group with Stentless Xenograft implantation, no complications related with the myocardium protection in the postoperative period occurred despite the long cross-clamp time.

In the literature, there are no level I or IIa evidences of better hemodynamic performance, LV mass regression, surgical risk and late outcomes. Currently, stentless bioprostheses are recommended in young and active patients with impaired LV function and small aortic annulus. On the other side, stentless bioprostheses are not generally recommended to all patients[7].

Bioprostheses for transcatheter aortic valve implantation does not have long-term outcomes[23]. Modification of stentless bioprostheses used in the transcatheter technique (TAVI) should be restricted to patients with serious comorbidity or older patients contraindicated to conventional aortic valve replacement. Also, autologous pericardial stentless valves should be restricted to younger age groups[7,24].

The morphologic structure is protected after aortic bioprostheses implantation in the stentless xenograft. This is also important for future transcatheter interventions. Very low pressure gradients result in a rapid regression of LV hypertrophy. Westaby et al[25] focused on the mechanisms of Freestyle valve improvements. They found the hypertrophic regression and decreased wall thickness at the ventricular level. The physical dimensions remained the same. However, greater stroke volume was observed which was associated with greater effective orifice area at the outflow tract level.

Conclusions

Our randomized study has demonstrated the benefits of stentless valves in manner of aortic valve gradients and effective orifice areas when compared with stented valves. These are important parameters, which have a positive impact on rapid regression of left ventricular hypertrophy. Further studies are needed with long follow-up to differentiate the effects of valve type.

Conflict of Interest

We declare that we have no conflicts of interests in the authorship or publication of this contribution.

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