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Mid-term results of Biological Bentall using a larger valve implantation technique

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ABSTRACT

The present study evaluated our modified technique for placing a valve one size larger for Biological Bentall (Bio-Bentall) with a stented valve using a double sawing ring technique with a comparison to classical Bio-Bentall with a stent-less valve. Between December 2001 and July 2017, 44 patients (10 stent-less and 34 stented) with Bio-Bentall were included in this study. The early and mid-term surgical outcomes and re-operation free rates, including the structural valve deterioration (SVD) rate, were investigated. The mean follow-up duration was 69 months. There were two in-hospital mortalities in the stent-less group and one in the stented group, showing no significant difference. The survival at 1, 5 and 10 years was 80%, 50% and 30% in the stent-less group and 85%, 77% and 71% in the stented group, respectively, with a significant difference. There were no cases of SVD occurrence in either group. Freedom from re-operation at 1, 5 and 10 years was 100% at all points in the stent-less group and 100%, 96% and 96% in the stented group, respectively, without significance. The mean pressure gradient through the aortic valve according to the most recent echocardiogram was 8.1 mmHg in the stent-less group and 15.8 mmHg in the stented group, without significance. Our modified technique for Bio-Bentall showed a feasible short- and mid-term survival compared to classical stent-less Bio-Bentall. Both techniques had a good outcome concerning SVD occurrence and the re-operation-free rate with a low-pressure gradient in the aortic position.

Keywords: Biological Bentall, aortic annulus degeneration

Abbreviations:
Bio-Bentall: Biological Bentall
SVD: structural valve deterioration
CPB: cardiopulmonary bypass
PCPS: peripheral cardiopulmonary support

INTRODUCTION

The Bentall operation for aortic annulus dilatation is a procedure established by Bentall and De Bono in 1968 involving root replacement with a composite graft wherein a mechanical valve

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and artificial graft are sutured in advance.[1] Since its establishment, several modified versions of this method for coronary artery reconstruction, such as the Cabrol technique,[2] Pieler technique[3] and Button technique (Carrel Patch technique),[4,5] have been introduced, and the long-term outcome has consequently improved. However, the Bentall operation remains the most popular and standardized procedure.

In the 1990s, a technique for preserving the normal aortic valve was introduced; David et al[6] reported in 1992 the "Reimplantation technique", which involves excising the aneurysmal portion of the ascending aorta and sinuses of Valsalva while leaving the aortic valve leaflets and some of the arterial wall attached to the left ventricular outflow tract, after which the aortic valve is reimplanted inside a Dacron graft. One year later, in 1993, Yacoub et al[7] reported the "Remodeling technique", which involves cutting the aneurysmal portion of the sinuses of Valsalva into three flaps while leaving the aortic valve leaflets and reshaping the aortic annulus with a Dacron graft. Since then, aortic valve sparing techniques have become globally implemented.

The Biological Bentall method, called "Bio-Bentall" in shorthand, using biological stented valves or stent-less valves has been introduced for elderly patients in whom the aortic valve is degenerated or complicated with severe aortic valve regurgitation.[8] The early clinical results of a preassembled stent-less valved-conduit incorporating artificial sinuses of Valsalva (BioValsalvaTM) was reported to have excellent hemodynamic performance and low morbidity in 2008.[9]

In 2001, we began performing Bio-Bentall using a free style stent-less valve (Medtronic Inc., Minneapolis, MN, USA) as a full-root technique anastomosed with a Hemashield graft (Hemashield Microvel Double Velour®; Meadox Medicals, Inc., Oakland, NJ, USA) at our institution.

However, since 2008, several reports have described negative short-term results, including early SVD occurrence, when using stent-less valves,[10-12] so we have switched to the double sewing ring technique in order to place one size larger valve, made by a biological valve and Valsalva Tube graft (Gelweave, Valsalva-prosthesis, Vascutek, Terumo, Scotland, UK).[13]

MATERIAL AND METHODS

Patients

The present study was a single-center, retrospective observational study including 44 consecutive patients who underwent aortic root replacement using a biological valve connected to an artificial graft between December 2001 and July 2017. Patients were divided into 2 groups based on their receipt of a stent-less valve (n=10) or stented valve (n=34). The study was approved by the institutional review board, which waived the need for individual patient consent.

The age indication for the Bio-Bentall is ≥ 65 years old, which is the same indication for a biological valve. Patients < 65 years of age can also be indicated for Bio-Bentall when hoping for a future pregnancy or with no desire to take anti-coagulation agents.

The indication for root surgery was chronic aortic degenerative root aneurysms with aortic valve insufficiency in 31 and aortic dissection in 12, of which 5 were acute and 7 chronic aortic dissection. Six patients in the stented group had connective tissue disorder: Marfan syndrome in four and aortitis syndrome in two. Fourteen patients (32%) had a history of cardiac or aortic operation. Concomitant operations were performed as follows: four coronary artery bypass grafts, five mitral valve operation, one tricuspid valve operation, five total arch replacements, five hemi-arch replacements and two maze operations. The other patient demographics for each group are listed in Table 1. The early and mid-term surgical outcomes and re-operation-free rates, including the structural valve deterioration (SVD) rate, were investigated.

Table 1 Preoperative Patient Characteristics

Variable	Over-all (n=44)	Stent-less (n=10)	Stented (DSR) (n=34)	P value
Age	67±12	72±6	65±14	0.118
Age>65	34 (77%)	10 (100%)	24 (70%)	0.218
Gender (Male)	33 (75%)	8 (80%)	25 (74%)	0.434
DM	4 (9%)	2 (20%)	2 (6%)	0.172
Hyperlipidemia	12 (27%)	3 (30%)	9 (26%)	0.826
Renal failure	1 (2%)	1 (10%)	0	0.062
Hemodialysis	1 (2%)	1 (10%)	0	0.062
Creatinine	1.06±1.18	1.67±2.6	0.9±0.2	0.081
Hypertension	30 (68%)	9 (90%)	21 (62%)	0.092
COPD	2 (4.5%)	0	2 (6%)	0.432
Previous Neurological event	2 (4.5%)	0	2 (6%)	0.432
Root aneurysm	31 (70%)	7 (70%)	24 (71%)	0.985
Aortic dissection (acute)	12(5) (27%)	3(1) (30%)	9(4) (26%)	0.835
Marfan syndrome	4 (9%)	0	4 (21%)	0.255
History of CVD	14 (32%)	4 (40%)	10 (29%)	0.527

Preoperative patient characteristics of the overall group, Stent-less group and Stented group
DM: Diabetes mellitus,
COPD: Chronic obstructive pulmonary disease
CVD: cardiovascular disease

Transition of composite graft

Bio-Bentall using a freestyle stent-less valve (Medtronic Inc.) as a full-root technique anastomosed with a Hemashield graft (Hemashield Microvel Double Velour®; Meadox Medicals, Inc.) was used for the first time in 2001. Since then, 10 stent-less valves using the full root technique have been used for Bio-Bentall, including 7 freestyle valves and 3 Prima Plus valves (Edwards Life Science, Irvine, CA, USA). The double sewing ring technique[13] performed using a biological valve connected to a Valsalva Tube graft (Gelweave, Valsalva-prosthesis, Vascutek; Terumo) has been performed in 34 patients since 2008. The composite graft is created as follows: the Valsalva graft is first everted by pulling its proximal end upward and inward. The biological valve is then sutured at the free margin of the everted graft with a running 4-0 polypropylene suture.13 In the standard technique, the biological valve size is usually set to be 5 mm smaller than the graft size, but in this technique, the biological valve size is set to be 3 mm smaller than the graft size, which is one size larger than with the standard technique, because the skirt portion of the Valsalva graft has a sufficient area to support a larger valve. This technique is useful for cases of future re-operation to replace a degenerated bioprosthesis without replacing the whole Valsalva graft as well as for valve-in-valve technique with transcatheter aortic valve implantation. This approach also allows for the implantation of a sufficiently large valve for cases with a small aortic root.[14]

Surgical technique

All operations were performed via standard median sternotomy using cardiopulmonary bypass (CPB) and cannulation of the ascending aorta, aortic arch or femoral artery with either a single

Table 2 Biological Valve and Graft

Valve	Valve size (mm)	Heamashield	Gelweave Valsalva	J graft	Triplex	Total
Freestyle	21	1				1
	23	1				1
	25	2			1	3
	27	2				2
Prima-plus	19	1				1
	23	1				1
	25	1				1
CEP	23		4			4
	25		5			5
	27		4			4
Magna-ease	21		1			1
	23		6	2		8
	25		10	1		11
Trifecta	25			1		1

The details concerning the selection of the biological valve and graft size

atrial or bicaval drainage, depending on the concomitant procedure. Mild, moderate or deep hypothermia was applied, also depending on the concomitant procedure. Cardiac arrest was achieved by antegrade or retrograde approaches and sometimes selective coronary perfusion by blood cardioplegic solutions. After aortic clamping, the diseased ascending aorta and aortic valve were completely resected, and debridement of the native annulus and aortic root was performed. At the same time, both coronary buttons were mobilized. After sizing of the annulus, the appropriate size of the composite graft was selected.

The details concerning the selection of the biological valve and graft size are shown in Table 2. For proximal anastomosis, multiple single, everting pledget-reinforced U-stitches (Ethibond 2-0; Ethicon, Norderstedt, Germany) are placed first from the area over the area over the aortic wall to underneath the aortic annulus, picking up the muscles of the left ventricle. These mattress sutures are made by the double-layered of the deep aortic annulus and the double-layered of the composite graft.[13] Proximal sutures are made using double-folded aortic sutures and double-folded graft sutures.[15] This approach results in a strong folding effect to prevent bleeding from the proximal anastomosis.

Statistical analyses

Data were collected and analyzed retrospectively. Statistical analyses were performed using the SPSS 22.0 statistical software package for Macintosh (SPSS Inc., Chicago, IL, USA). Quantitative variables approximating a normal distribution are presented as the means ± standard deviation (SD). The differences between the groups were evaluated by Student's t-test or the Mann-Whitney U test for continuous data, depending on the normality of the data, and the χ^2 or Fisher's exact test was used to compare categorical variables. A Kaplan-Meier analysis was used to analyze the survival. The significance of differences in the Kaplan-Meier survival was determined with the log-rank test. Two-tailed P values < 0.05 were considered significant.

RESULTS

The mean age of the stent-less group was higher (72 ± 6 years old) than that of the stented group (65 ± 14 years old) without significance. A total of 30% of the patients in the stented group were < 65 years old.

Operative data

Associated surgical procedures and operative data are listed in Table 3. About 15% of the patients underwent an urgent operation. One third of the patients had a history of cardiac operation. An aortic cross clamping time exceeding 180 minutes was associated with multiple concomitant procedures, including 10 cases of arch replacement (1 case in the stent-less group and 9 in the stented group). Twenty cases required some degree of brain protection, with 16% undergoing circulatory arrest, 52% selective cerebral perfusion and 32% retrograde cerebral perfusion.

Early outcomes

Mortality within 30 days occurred in 1 case in the stent-less group due to cerebral hemorrhaging. This patient was complicated with a tissue disorder and required re-operation seven times for valve detachment. The cause of the last operation was cardiogenic shock due to mitral valve detachment and the suture line detachment of the previous mechanical Bentall. This patient had undergone Bio-Bentall using a freestyle valve and mitral valve replacement with a long aortic cross clamping time and operation time. The patient developed unstable hemodynamics and required peripheral cardiopulmonary support (PCPS).

Table 3 Operative Data & Concomitant Procedure

Variable	Over-all (n=44)	Stent-less (n=10)	Stented (DSR) (n=34)	P value
Urgency	6 (14%)	1 (10%)	5 (15%)	0.703
History of Cardiac Surgery	14 (32%)	4 (40%)	10 (29%)	0.577
Operation time (min)	560±222	512±239	575±219	0.433
CPB time (min)	278±135	270±137	280±136	0.833
ACC time (min)	188±64	179±78	188±61	0.709
ACC time (min) >180	22 (50%)	4 (40%)	18 (53%)	0.472
Brain protection	20 (43%)	5 (5%)	15 (44%)	0.743
Concomitant Procedure	20 (43%)	4 (40%)	16 (47%)	0.694
CABG	4 (9%)	2 (20%)	2 (6%)	0.172
Mitral Valve operation	6 (14%)	1 (10%)	5 (15%)	0.703
Tricuspid operation	1 (2%)	0	1 (3%)	0.583
Arch Replacement (Total/Hemi)	12(6/6) (27%)	1(1/0) (10%)	11(5/6) (32%)	0.163
Maze	3 (7%)	0	3 (9%)	0.331

Associated surgical procedures and operative data
CPB: Cardiopulmonary bypass,
CC: Aortic cross clamp
CABG: Coronary aortic bypass grafting

In-hospital mortality occurred in two cases in the stent-less group and one case in the stented group. One of these cases had acute type A aortic dissection with an intimal tear in the aortic root and had undergone Bio-Bentall and additional CABG because of an extended tear into the coronary button anastomosis. This patient also developed unstable hemodynamics and ultimately required PCPS. The cause of death in another case was acute respiratory distress syndrome.

The post-operative complications are summarized in Table 4. Re-exploration and neurological deficit showed acceptable occurrence rates in both groups without any significant differences. A long ventilation time (> 72 h) was required in 18 patients, and the most frequent complications was atrial fibrillation (43% of the patients). There were no significant differences between the two groups in post-operative complications.

Late outcomes

There were 30 survivors (68%), all of whom were included in the follow-up study. Long-term follow-up was performed for a mean 65 ± 46 months and median 54 months. During the follow-up, 12 patients (27%) died, with their causes of death listed below. Death in 58% of the patients (n=7) was not valve- or cardiac-related, including 1 case of brain infarction, 1 of sepsis, 2 of stomach cancer, 1 of pneumonia, 1 of leukemia and 1 of descending aortic rupture. The cause of death in the other 42% of the patients (n=5) was unknown.

The mid-term findings for the biological aortic valve performance for the alive cases (26 cases) are shown in Table 5. The mean follow-up duration for overall cases was 58 ± 46 months for overall cases and 107±80 months for the stent-less group and 54 ± 42 months for the stented group. The longest follow-up duration was 163 months in the stent-less group. The peak pressure gradient through the biological valve was 15 ± 7.7 mmHg for overall cases and 8.1 ± 1.3 mmHg in the stent-less group and 15.8 ± 7.7 mmHg in the stented group.

An 89-year-old woman who had undergone Bio-Bentall with a 25-mm freestyle valve (Medtronic Inc.) 17 years ago (stent-less group) had the longest follow-up. She showed a good performance for the biological valve, with a peak gradient across the biological aortic valve of 9 mmHg, mean gradient of 4.2 mmHg and peak velocity of 1.5 m/s. An 83-year-old man who had undergone Bio-Bentall with a 25-mm Carpentier-Edwards Perimount valve (Edwards Life Science) using the double sewing ring technique 11 years ago also showed a good performance for the biological valve, with a peak gradient across the biological aortic valve of 10 mmHg and peak velocity of 1.6 m/s.

The mid-term survival at 1, 5 and 10 years was 84%, 74% and 57% overall; 80%, 50% and 30% for the stent-less group; and 85%, 77% and 71% for the stented group, respectively, with a significant difference noted between the 2 groups (p=0.031) (Figure 1). The mid-term survival between the patients < 65 years old and ≥ 65 years old is presented in Figure 2. There were no significant differences in the midterm survival, but the younger group tended to have a better survival within 5 years than the older group.

Only one patient required reoperation for infectious endocarditis in the stented group, and none required it in the stent-less group. The freedom from re-operation at 1, 5 and 10 years was 100%, 100% and 100% in the stent-less group and 100%, 96% and 96% in the stented group, respectively, with no significant difference (Figure. 3). There has been no SVD in our series so far.

Table 4 Post-Operative Data

Variable	Over-all (n=44)	Stent-less (n=10)	Stented (DSR) (n=34)	P value
30 days mortality	1 (2.2%)	1 (10%)	0	0.062
Hospital mortality	3 (6.8%)	2 (20%)	1 (3%)	0.06
Re-exploration	2 (4.5%)	0	2 (6%)	0.432
Neurological deficit	2 (4.5%)	1 (10%)	1 (3%)	0.346
Renal failure	3 (6.8%)	1 (10%)	2 (6%)	0.65
Dialysis	1 (2.2%)	0	1 (3%)	0.583
Long ventilation (>72h)	9 (18%)	1 (10%)	8 (24%)	0.351
Tracheostomy	2 (4.5%)	0	2 (6%)	0.432
Pneumonia	4 (9%)	1 (10%)	3 (9%)	0.909
Atrial fibrillation	19 (43%)	3 (30%)	16 (47%)	0.338
IABP	1 (2.2%)	0	1 (3%)	0.583
PCPS	2 (4.5%)	1 (10%)	1 (3%)	0.346

The post-operative data, including mortality and complications
IABP: Intra-aortic balloon pumping,
PCPS: Percutaneous cardio pulmonary support

Table 5 Midterm results of Biological valve procedure

Variable	Over-all (n=26)	Stent-less (n=3)	Stented (DSR) (n=23)	P value
Mean follow-up duration (month)	58±46 (2–163)	107±80 (50–163)	54±42 (2–136)	0.124
Aortic valve regurgitation	Mild 4 Trace12 None 10	Trace 3	Mild 4 Trace 9 None 10	Not available
Peak PG (mmHg)	15±7.7	8.1±1.3	15.8±7.7	0.179
Peak velocity (m/s)	1.88±0.5	1.4±0.1	1.93±0.5	0.147

The midterm results of the biological valve performance
PG: Pressure gradient

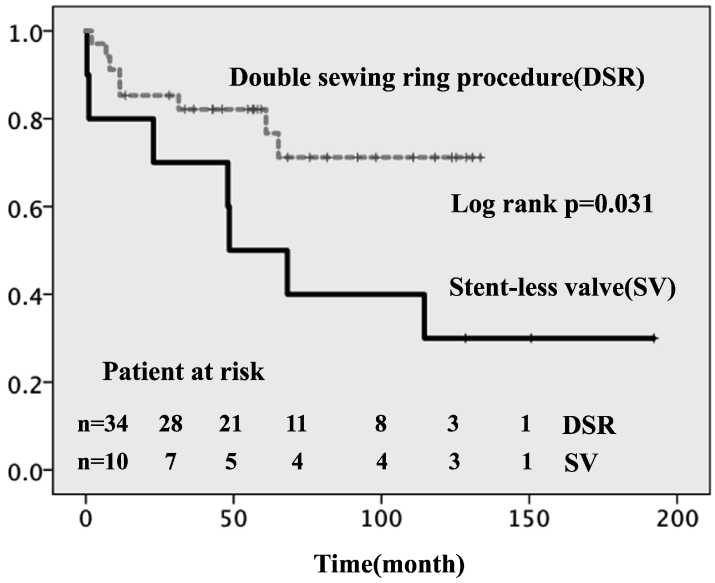

Fig. 1 Survival Curve (Technique)
The comparison between the outcomes of the stent-less and stented valves with the double sewing ring technique.

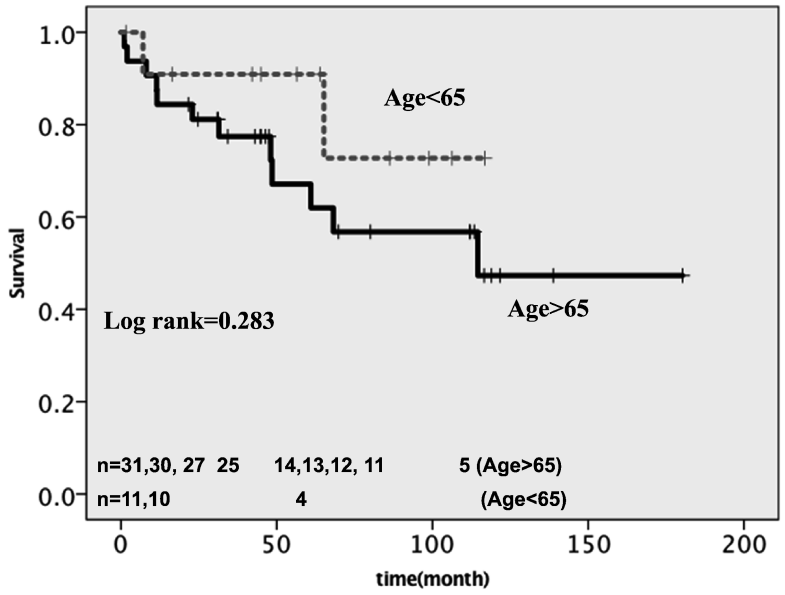

Fig. 2 Survival Curve (Age)
The comparison of patients < 65 and ≥ 65 years old

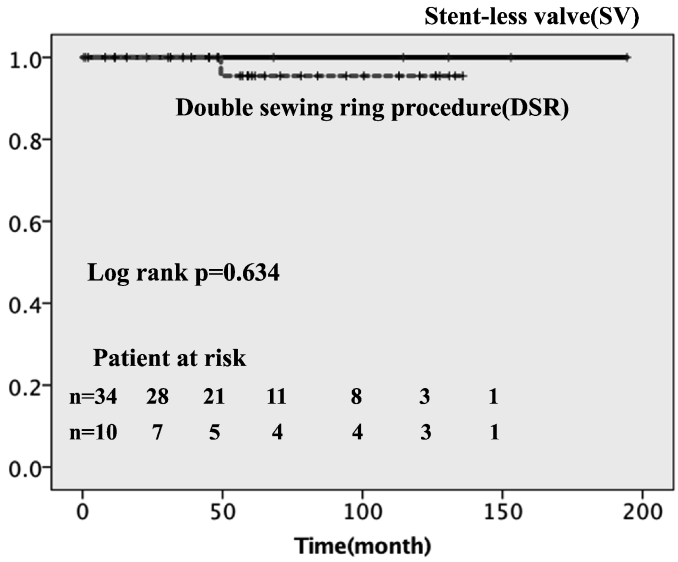

Fig. 3 The freedom from re-operation
The freedom from re-operation at 1, 5 and 10 years in each group.

DISCUSSION

The surgical outcome of the Bentall procedure has been considered the gold standard in the surgical treatment of combined aortic valve and ascending aorta diseases since Bentall and DeBono first described the technique for complete replacement of the ascending aorta and aortic valve with reimplantation of the coronary arteries in 1968.[1] Several modified techniques for coronary reconstruction have reduced the intra-operative bleeding and improved the peri-operative morbidity and mortality.[2-5] The selection of a mechanical or biological valve is made using the same selection criteria as those for aortic valve replacement. However, young patients who wish to avoid the need for life-long anti-coagulation or who desire to become pregnant may choose Bio-Bentall. SVD of a biological valve might be the major concern with Bio-Bentall. For the Freestyle stent (Medtronic Inc.) in particular, the Bio-Bentall procedure has been found to be associated with several issues, including pseudoaneurysm formation and leaflet degeneration via an immune-mediated reaction (16–19). For this reason, we have switched to the double sawing technique using a stented biological valve.

Of note, there were no cases of SVD in our series. One dialysis patient in the stent-less group was at risk of developing SVD in the future, but this patient unfortunately died four years after the operation. Dialysis was shown to be a significant predictor of SVD in our previous report.[20] The cases with the longest follow-up in our study (17 years) received stent-less Bio-Bentall and has maintained beautiful valve motion without any SVD. It has been 11 years since we started performing the double sewing ring technique, and case in which stented Bio-Bentall was performed beyond 11 years ago have also maintained beautiful motion without any SVD thus far. No re-operation for SVD was required in either group. Stent-less valves have a larger effective valve orifice area than stented valves. However, placing a valve one size larger in the Valsalva graft may have helped preserve the valve function for long time in our series.

The review report of Castrovinci et al[21] regarding 14 studies with 1882 patients showed that the long-term survival at 1, 2, 3, 5 and 10 years was 88%, 86%, 82%, 76% and 58%, respectively.

That same report found that, among 10 studies with 1216 patients, the freedom from reoperation at 1, 2, 3 and 5 years was 96%, 94%, 93% and 90%, respectively. Furthermore, 3 studies in that report described the freedom from prosthesis endocarditis at 1, 2, 3 and 5 years as 99%, 98%, 96%, and 94%, respectively. These data were almost the same as the findings from the present study. However, that review included no precise data regarding SVD occurrence. More than 15 or 20 years' follow-up might be needed in order to discuss the long-term durability of biological valves and SVD occurrence.

Another report from a Toronto group[22] described the results of a comparison study between aortic valve-sparing root replacement and mechanical Bentall and Bio-Bentall. That study showed that the aortic valve-sparing procedure was associated with reduced cardiac mortality and valve-related complications compared with mechanical Bentall and Bio-Bentall. However, the Bio-Bentall group included an extremely large number of aortic insufficiency cases and a moderate number of cases with a low cardiac function (ejection fraction < 40%), so it is difficult to discuss whether or not Bio-Bentall had a less mortality and morbidity. That report showed that the rates of aortic valve reoperation were higher among patients undergoing Bio-Bentall than mechanical Bentall. There was no precise description regarding the reoperations which types of biological valve has high incidence, including the Freestyle porcine root, Hancock II (Medtronic Inc.), Toronto stent-less root (St. Jude Medical Inc., St. Paul, MN, USA), homograft and others. The valve durability might differ among biological valves.

However, even if of these valves does have a unique durability, the option to perform the valve-in-valve technique using transcatheter aortic valve implantation in cases of prosthesis failure is very useful.[23-24] As the valve we placed using the double sawing technique was one size larger than that with the usual Bio Bentall procedure, we can also use a one-size-larger valve in cases using the valve-in-valve technique, which may help extend the overall durability.

The study limitations include the small number of patients, the different numbers of patients and background characteristics between the two groups, the different operation durations between the two groups, and the retrospective observational design. A randomized controlled study may be needed to compare the effectiveness of both techniques. No assertive conclusions can be drawn in this study.

CONCLUSIONS

The Bio-Bentall procedure showed feasible short- and long-term outcomes with a low rate of re-operation in our series. Even if the time of reoperation for failed prosthetic valve, valve in valve technique is useful. The further development of the Bio-Bentall procedure might result in a longer durability, even exceeding 20 years depending on the technique.

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CONFLICT OF INTEREST

There was no conflict of interest.

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