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Original Article

Experience of Balloon Aortic Valvuloplasty for Severe Aortic Stenosis in Patients Scheduled for Open Surgery for Chronic Limb-Threatening Ischemia

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Objectives: To estimate the effectiveness of balloon aortic valvuloplasty (BAV) for severe aortic stenosis (SAS) in patients scheduled for open surgery for chronic limb-threatening ischemia.

Materials and Methods: Clinical data of patients from 2012 to 2018 were retrieved and summarized. The early outcomes and survival after BAV and open bypass were retrospectively investigated.

Results: BAV was performed on seven dialysis patients. One patient died of mesenteric infarction 3 days after BAV; however, six patients were able to undergo open bypass at an average of 10 days (7–19 days) after BAV. One patient died of hemorrhagic shock before the wound healed; five patients underwent limb salvage. Four of these five patients could not undergo surgical aortic open valve replacement owing to advanced age or poor cardiac function and died within 2 years. Only one patient who underwent radical surgery after a bypass survived more than 4 years.

Conclusion: BAV enabled open surgery and limb salvage in patients with SAS. Although BAV alone cannot ensure long-term survival, the procedure will continue to be important as a bridge technique to radical surgery, such as transcatheter aortic valve implantation and aortic valve repair, which are often avoided owing to infection.

Keywords: BAV, severe AS, open bypass, CLTI, end-stage renal disease

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Introduction

Aortic stenosis (AS) has a high-risk index among cardiac complications when performing noncardiac surgery (NCS), and it is recommended that radical surgery for AS precede NCS if the latter is elective.[1)] For patients with severe AS (SAS) and without enough time for radical surgery, balloon aortic valvuloplasty (BAV) may be performed if the proposed NCS is a high-risk procedure.[2)]

The operative risk of patients with SAS who require surgical revascularization for chronic limb-threatening ischemia (CLTI) is very high; most patients have multiple comorbidities, and bypass surgery for peripheral artery disease (PAD) is deemed a high-risk procedure.[2)] Moreover, revascularization for patients with CLTI must be performed as early as possible; therefore, BAV may precede the surgery as a bridge to radical surgery.[2)] However, to the best of our knowledge, reports summarizing cases of SAS scheduled for open bypass surgery for CLTI are still lacking in Japan.

Herein, we report seven cases of patients who underwent BAV before scheduled open surgery for CLTI, with early and late outcomes, and consider the issues associated with this treatment for patients with CLTI and SAS.

Materials and Methods

This study was approved by the institutional review board of Saiseikai Yahata General Hospital, Kitakyushu City,

Japan (approval number: 193). The requirement for informed consent was waived because all patients had died before the study was performed. A total of seven patients (four men and three women) underwent BAV for SAS before open surgery for CLTI at Steel Memorial Yawata Hospital, Kokura Memorial Hospital, and Saiseikai Yahata General Hospital between 2012 and 2018. All seven were dialysis patients. The patients' data, namely preoperative demographics and clinical history, echocardiography findings before and after BAV, operative information, and outcomes during the follow-up period, were retrospectively reviewed.

Strategy for SAS and open surgery for CLTI

Patients with SAS, which was diagnosed using preoperative echocardiography, underwent endovascular treatment (EVT) as the initial treatment. However, open surgery was selected for patients whose arterial anatomy was considered to be unsuitable for EVT (at the discretion of the vascular surgery team) or if EVT was unsuccessful. The vascular surgery team then consulted anesthesiologists and cardiologists about the risk of surgery and the necessity of BAV, which was performed as agreed upon in the consultation.

The BAV procedures

There are two methods for performing BAV: antegrade and retrograde. In the antegrade method, the femoral vein is punctured, and a guidewire is passed from the right atrium through the atrial septum to the left atrium, left ventricle, and aortic valve to dilate the balloon. In the retrograde method, the femoral artery is punctured, and a guidewire is passed via the aorta to the aortic valve, where the balloon is dilated. Each method has advantages and disadvantages. The advantage of the antegrade method is that there are fewer cerebral infarctions and fewer vascular complications at the puncture site. Additionally, the resulting aortic valve dilation after BAV is approximately 20% greater with the antegrade method than with the retrograde method. However, the disadvantages are that the antegrade method is more complicated and difficult compared with the retrograde method, and the procedure time is longer. Therefore, despite the advantages of the antegrade method, the retrograde method, with its shorter procedure time, is more likely to be selected for elderly patients or patients in poor general condition.

Six patients were temporarily transferred to another institute for BAV, and one patient underwent BAV in the hospital where the open surgery for CLTI was scheduled. One patient died of mesenteric infarction 3 days after BAV; therefore, a total of six patients underwent open surgery.

Follow-up after discharge

Patients were followed up at 1- to 3-month intervals to check the indicated tissue loss and the graft patency with physical examination, ankle-brachial pressure index, and duplex ultrasonography. When duplex ultrasonography showed graft stenosis with peak systolic velocity >350 cm/s or the pulse of the graft was palpated as obviously weak, angiography was recommended, and intervention was performed for graft salvage.

Endpoints

Death and major cardiovascular events were set as primary endpoints, and cure of the indicated wound and major amputation were set as secondary endpoints.

Definitions

The criteria for diagnosing SAS were as follows: peak aortic velocity (Vmax) >4.0 m/s, and/or mean pressure gradient (mPG) >50 mmHg, and/or aortic valve area (AVA) <1.0 cm^2. Major adverse cardiovascular events were defined as cardiac events (myocardial infarction, angina, lethal arrhythmia, heart failure, sudden death, and intervention for coronary artery disease, heart valve disease, and arrhythmia) and cerebral events (cerebral infarction, cerebral hemorrhage, transient ischemic attack, or intervention for cerebral ischemia).

Statistics

Continuous and categorical variables were expressed as median [interquartile range] and percentage, respectively. Survival time was calculated from the day of BAV.

Results

The details of each patient are summarized in **Tables 1**–**5**.

Patients' characteristics

The median [25th, 75th percentile] age was 72 [70, 82] years, and males accounted for 57% of the patients. Five patients (71%) had tissue loss and were classified as wound, ischemia, foot infection (WIfI) stage 4. The median ankle-brachial pressure index and skin perfusion pressure were 0.44 [0, 0.7] and 17 [9, 27] mmHg, respectively. The comorbidity rates were 57% for hypertension, 43% for diabetes mellitus, 14% for dyslipidemia, 71% for coronary artery disease, 0% for atrial fibrillation, 29% for cerebrovascular disease, 33% for current smoking, and 100% for end-stage renal disease. Three patients (43%) had a history of malignancy. Four patients (57%) were classified as high-risk in accordance with the Project or Ex-vivo Vein Graft Engineering via Transfection III score. One of five patients who was ambulatory before bypass surgery required a wheelchair postoperatively, while the

Table 1 Demographics and clinical history of patients

Case	Age, sex	Rutherford/ WIfI	ABI	SPP	HT	DM	Dyslipidemia	CAD	Af	CVD	COPD	ESRD	Currently smoking	Malignancy	PREVENT-III	Ambulatory status before bypass	Ambulatory status after bypass	GNRI
1	67, male	5/4	0.70	9	yes	no	no	yes	no	yes	no	yes	no	yes kidney	8	ambulatory	wheelchair	87.5
2	82, male	5/4	0	11	yes	yes	no	yes	no	no	yes	yes	yes	no	10	ambulatory	ambulatory	89.0
3	72, male	6/4	0.44	27	yes	yes	no	yes	no	no	no	yes	yes	yes stomach	8	ambulatory	ambulatory	80.2
4	93, female	4/2	0	2	no	yes	no	yes	no	no	yes	yes	no	no	6	ambulatory	ambulatory	83.1
5	79, female	5/3	0.60	17	yes	no	no	no	no	no	no	yes	no	no	7	wheelchair	wheelchair	89.8
6	70, female	4/2	1.12	40	no	no	no	no	no	no	no	yes	no	no	5	ambulatory	ambulatory	89.6
7	88, male	6/4	0	25	no	no	yes	yes	no	yes	?	yes	no	yes meso-thelioma	8	ambulatory	-	77.7

WIfI: risk stratification based on Wound, Infection, and foot Infection; ABI: ankle-brachial pressure index; SPP: skin perfusion pressure; HT: hypertension; DM: diabetes mellitus; CAD: coronary artery disease; Af: atrial fibrillation; CVD: cerebrovascular disease; COPD: chronic obstructive pulmonary disease; ESRD: end-stage renal disease; GNRI: geriatric nutritional risk index; PREVENT-III: the Project of Ex-vivo Vein Graft Engineering via Transfection III score

Table 2 Echocardiographic findings before and after BAV

Case	Before BAV					After BAV				
	Vmax	mPG	AVA	AVAI	EF	Vmax	mPG	AVA	AVAI	EF
1	5.01	53	0.89	0.57	70	4.73	56.7	0.95	0.60	61
2	4.10	36	0.77	0.54	75	3.70	29	0.81	0.57	69
3	3.50	22	0.64	0.42	38	2.71	16.8	0.77	0.50	36
4	3.41	29	0.48	0.33	52	2.89	18.8	0.85	0.58	57
5	5.01	58	0.76	0.56	60	4.33	47	0.8	0.58	64
6	3.77	31.3	1.27	0.82	40	2.83	17.5	1.59	1.03	40
7	5.29	55	0.53	0.42	61	3.73	26.2	0.72	0.57	57

BAV: balloon aortic valvuloplasty; Vmax: peak aortic velocity; mPG: mean pressure gradient; AVA: aortic valve area; AVAI: aortic valve area index; EF: ejection fraction

Table 3 BAV findings

Case	Major devise	Approach method punctured vessel	Anesthesia	Length of time (Min)	Symptoms before BAV	Complication after BAV	BAV to discharge (Days)
1	Inoue Balloon	Antegrade BAV Rt. femoral vein Lt. femoral artery	Local + Intravenous anesthesia	71	Nothing	Pneumonia	4
2	Inoue Balloon	Antegrade BAV Rt. femoral vein Lt. femoral artery	Local anesthesia	148	Nothing	Nothing	4
3	Inoue Balloon	Antegrade BAV Rt. femoral vein Lt. femoral artery	Local + Intravenous anesthesia	96	Nothing	Nothing	1
4	Inoue Balloon	Antegrade BAV Rt. femoral vein	Local + Intravenous anesthesia	82	Nothing	Nothing	6
5	Inoue Balloon	Antegrade BAV Rt. femoral vein	Local + Intravenous anesthesia	140	Nothing	Nothing	4
6	Inoue Balloon Z-MED II	Retrograde BAV Lt. femoral artery	Local + Intravenous anesthesia	56	Chest pain	Nothing	2
7	Inoue Balloon	Antegrade BAV Rt. femoral vein Rt. brachial artery	Local + Intravenous anesthesia	147	Nothing	Mesenteric ischemia	2

BAV: balloon aortic valvuloplasty; Min: minute

remaining four patients were ambulatory after bypass surgery. On the basis of the geriatric nutritional risk index (**Table 1**), the nutritional status of all patients was classified as moderate or poor.

Echocardiographic findings before and after BAV

Before BAV, Vmax was 4.1 [3.5, 5.29] m/s, mPG was 36 [29, 55] mmHg, AVA was 0.76 [0.53, 0.89] cm^2, aortic valve area index (AVAI) was 0.54 [0.42, 0.57] cm^2/m^2, and the ejection fraction was 60% [40%, 70.2%]. Aortic valve calcification was evident in all cases. After BAV, Vmax was 3.7 [2.83, 4.33] m/s, mPG was 26.2 [17.5, 47] mmHg, AVA was 0.81 [0.77, 0.95] cm^2, AVAI was 0.58 [0.51, 0.6] cm^2/m^2, and the ejection fraction was 57% [40%, 64%] (**Table 2**).

BAV for SAS

In this series, the antegrade method was selected in six cases and the retrograde method in one case. The Inoue balloon (Toray Industries, Tokyo, Japan) was selected for all cases, and Z-MED (PFM Medical USA, Inc., Carlsbad, CA, USA) was added for one patient (case 6). All patients received local anesthesia, and intravenous anesthesia was added in six cases (except 2). The average procedure time was 105 [56–148] min, and the average time from the procedure to discharge was 3.3 [1–6] days. Prior to BAV, one patient (case 6) had chest pain as a symptom. Complications after BAV comprised pneumonia in one patient (case 1) and death from mesenteric infarction in one patient (case 7) 3 days after BAV (**Table 3**).

Open surgery for CLTI

One patient (case 4) underwent endarterectomy with patch angioplasty of the common femoral artery and endovascular intervention of the iliac artery. The remaining five patients underwent paramalleolar artery bypass surgery (**Table 4**).

Clinical course after BAV

Six patients (cases 1–6) underwent open surgery for CLTI,

Table 4 Operative findings

Case	Reason for surgery	BAV to ope. (days)	Performed ope.	Anesthesia	Ope. time	Bleeding volume
1	EVT failure	11	BKPOP-mPL bypass	General	425	150
2	EVT failure	7	F-PT bypass	Block	295	160
3	Anatomy	19	F-Dp bypass	General	418	470
4	EVT failure	9	CFA patch & iliac POBA	General	130	20
5	EVT failure	7	BKPOP-Dp bypass	General	223	130
6	Recurrence of CLTI after EVT	8	AKPOP-PT bypass	General	185	60
7	Anatomy		Not performed			

BAV: balloon aortic valvuloplasty; ope.: operation; EVT: endovascular treatment; BKPOP: below the knee popliteal artery; mPL: medial plantar artery; F: femoral artery; PT: posterior tibial artery; Dp: dorsal pedis artery; CFA: common femoral artery; POBA: plain old balloon angioplasty; CLTI: chronic limb-threatening ischemia; AKPOP: above the knee popliteal artery

Table 5 Postoperative course

Case	Postope. in-hospital event	Wound healing	Ope. to wound healing (days)	Major amputation	AVR Ope. To event (days)	MACE, Ope. To event (days)	Ope. To death (days)	Death cause
1	Graft infection	no		no	no		21	Hemorrhagic shock
2		yes	83	no	no	AMI, 557	557	AMI
3		yes	131	no	no		311	AHF
4		no wound		no	no		545	Sepsis
5		yes	48	no	no		145	Sudden death
6		no wound		no	yes, 388	AHF, 135; AMI, 388	1640	Cardiac amyloidosis
7				no				Mesenteric ischemia

Postope.: postoperative; Ope.: Operation; AVR: aortic valve replacement; MACE: major adverse cardiovascular events; AMI: acute myocardial infarction; AHF: acute heart failure

and five were discharged after successful limb salvage. One patient (case 1) died from hemorrhagic shock. He was found to have a surgical site infection 1 week after surgery. The infection spread to the deeper layers, and hemorrhage occurred following rupture of the infected graft 21 days after surgery. Despite early hemostasis and resuscitation attempts, his heartbeat was not recovered. Two cases died suddenly within 1 year of discharge, and two cases died within 2 years (one from acute heart failure and the other from sepsis secondary to infection of a newly formed gangrene of the contralateral limb). These four patients did not undergo additional intervention for AS. Cases 3 and 5, who died suddenly, were patients with tissue loss that had healed completely. However, they did not undergo radical surgery owing to very low cardiac function, with an original ejection fraction of $<40\%$. Additionally, cases 2 (83 years old) with tissue loss that had healed and 4 (93 years old) without tissue loss did not undergo radical surgery owing to advanced age. Case 6 was the only patient who underwent aortic valve repair (AVR) and coronary artery bypass grafting with a permanent pacemaker for acute myocardial infarction 13 months after open surgery for CLTI. The patient lived for approximately 4 years and died of cardiac amyloidosis (**Table 5**).

Discussion

We report on seven dialysis patients who underwent BAV for SAS before surgical revascularization for CLTI. One patient died from a complication of BAV before revascularization, and another died after revascularization without wound healing within 30 days after surgery. Limb salvage with wound healing was achieved in all five remaining cases. However, four patients died within 2 years after open surgery. Only one patient, who underwent AVR and coronary artery bypass surgery 13 months after open surgery, survived more than 4 years.

The goals of CLTI treatment are pain relief, wound healing, limb salvage, and quality of life improvement. To accomplish these goals, revascularization is essential. The current global vascular guidelines on the management of CLTI showed the algorithm for the revascularization strategy based on the patient risk, limb severity, and anatomic complexity of the disease approach and recommended EVT, a less invasive treatment, for high-risk patients.[3)]

It is well known that the risk of NCS for patients with AS is significantly high; therefore, it is recommended that NCS, if elective, be postponed until radical surgery for SAS has been performed.[1)] However, recent advancements in anesthesia and surgical techniques and perioperative management have made it possible to safely perform

NCS for patients with asymptomatic SAS.[4] The operative risk of NCS is based on the severity of AS (moderate vs. severe), the clinical status, and the invasiveness of surgery (mild or intermediate vs. severe).[5]

Most patients with CLTI cannot afford to have their NCS delayed until they have undergone radical treatment for SAS. They usually have several comorbidities, and bypass surgery for PAD is deemed a high-risk procedure,[2] which makes intervention for SAS before NCS inevitable. Accordingly, EVT is the first option; however, it is not always successful, and some patients have an arterial anatomy more suitable for bypass surgery. In all three institutes, we performed echocardiography for all patients who were scheduled to undergo open surgery for PAD and consulted with cardiologists.

In cases diagnosed with SAS, cardiac surgeons tend to avoid AVR in cases of tissue loss because of concerns about postoperative infection. Cardiologists similarly tend to avoid transcatheter aortic valve implantation (TAVI) in cases of tissue loss. Additionally, TAVI was not covered by health insurance for dialysis patients until February 2021 in Japan. As all patients in this series were dialysis patients, TAVI could not be performed in Japan during the study period. Therefore, BAV was the only option for patients such as those with CLTI who did not have time to spare for limb salvage. BAV was planned in accordance with the results of a multidisciplinary consultation among vascular surgeons, cardiologists, and anesthesiologists. In one case (case 6), the AS was moderate; however, BAV was recommended because the patient had cardiac symptoms.

Parikh et al. reported that the survival rate of patients with chronic kidney disease (CKD) who underwent BAV was poor and that PAD was one of the independent predictors of death.[5] Ben-Dor et al. demonstrated that the half-year mortality of high-risk or inoperable patients undergoing BAV was 50%, and AVA $<1\,cm^2$ after BAV was an independent predictor.[6] In the present series, six patients showed an AVA of $<1\,cm^2$ even after BAV, which might indicate the difficulty of BAV for dialysis patients.

TAVI has recently been approved for dialysis patients in Japan. However, the outcomes in patients with renal failure or valve calcification reported in Germany were poor,[7] and TAVI treatments for patients with advanced CKD and those with end-stage renal disease on hemodialysis are considered challenging.[8] Maeda et al. reported that in-hospital results were good, but various problems remained at mid-term follow-up.[9] Notably, our patients suffered from not only AS but also CLTI. It is important to remember the report of Malyar et al. showing that post-procedure morbidity and mortality after TAVI were high in patients with PAD, especially those with critical limb ischemia, regardless of the presence of CKD.[10] The results of this clinical report indicate that BAV may be advantageous as well as disadvantageous. Furthermore, the results suggested that long-term survival could not be expected without radical surgery for SAS. Ben-Dor et al. also concluded that the survival rate of patients undergoing only BAV was poor and that BAV as a bridge to TAVI or AVR is associated with better outcomes than BAV alone.[6]

The results of this series of open surgeries with BAV in dialysis patients with CLTI were satisfactory. The four cases in this series in which AVR as a radical procedure was not indicated (including three cases of wound healing) were cases before TAVI was covered by insurance for dialysis patients in Japan, and now that it is covered by insurance, TAVI as a radical procedure may well be indicated. However, because TAVI also tends to be avoided in cases with infection, the first step is to perform BAV to allow open surgery and complete wound healing. Subsequent radical surgery is considered to improve the prognosis of patients with CLTI and SAS. Therefore, BAV will continue to play an important role in cases with infection as a bridge procedure.

The present study had several limitations. First, the number of patients was too small for a definitive conclusion to be made on the treatment strategy for SAS in dialysis patients scheduled for open surgery for CLTI. Second, we were unfamiliar with the strategy or technique of BAV because it was entirely decided on by the cardiologists; therefore, we are unsure whether we should be satisfied with the seemingly incomplete results of BAV. Third, the decision to perform AVR in a patient with tissue loss depended on the consulting cardiac surgeon; other physicians may have been more willing to perform AVR.

Conclusion

BAV enabled open surgery for limb salvage in hemodialysis patients with severe AS. Although BAV alone cannot ensure long-term survival, the procedure will continue to play an important role as a bridge technique to radical surgeries, such as TAVI and AVR, which can be performed after complete wound healing.

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Conflict of Interest Declaration

None.

Author Contributions

Study conception: KT, SM
Data collection: all authors
Analysis: KT, SM
Investigation: KT, SM
Writing: KT
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors

References

1) Fleisher LA, Fleischmann KE, Auerbach AD, et al. 2014 ACC/AHA guideline on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2014; **130**: e278-333.
2) Halvorsen S, Mehilli J, Cassese S, et al. 2022 ESC guidelines on cardiovascular assessment and management of patients undergoing non-cardiac surgery. Eur Heart J 2022; **43**: 3826-924.
3) Conte MS, Bradbury AW, Kolh P, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. Eur J Vasc Endovasc Surg 2019; **58 1S**: S1-S109. e33.
4) Tashiro T, Pislaru S, Blustin JM, et al. Perioperative risk of major non-cardiac surgery in patients with severe aortic stenosis: a reappraisal in contemporary practice. Eur Heart J 2014; **35**: 2372-81.
5) Parikh PB, Novotny S, Jeremias A, et al. Impact of chronic kidney disease on mortality in adults undergoing balloon aortic valvuloplasty. Cardiovasc Revasc Med 2018; **19**: 448-51.
6) Ben-Dor I, Pichard AD, Satler LF, et al. Complications and outcome of balloon aortic valvuloplasty in high-risk or inoperable patients. JACC Cardiovasc Interv 2010; **3**: 1150-6.
7) Mas-Peiro S, Faerber G, Bon D, et al. Impact of chronic kidney disease in 29893 patients undergoing transcatheter or surgical aortic valve replacement from the German aortic valve registry. Eur J Cardiothorac Surg 2021; **59**: 532-44.
8) Adachi Y, Yamamoto M. Chronic kidney disease and transcatheter aortic valve implantation. Cardiovascular Intervention and Therapeutic 2022; **37**: 458-64.
9) Maeda K, Kuratani T, Mizote I, et al. Midterm outcomes of transcatheter aortic valve replacement in dialysis patients with aortic valve stenosis. Circ J 2019; **83**: 1600-6.
10) Malyar NM, Kaier K, Freisinger E, et al. Prevalence and impact of critical limb ischaemia on in-hospital outcome in transcatheter aortic valve implantation in Germany. EuroIntervention 2017; **13**: 1282-8.