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ORIGINAL ARTICLE
Cardiovascular Surgery

Mid-Term Clinical Outcomes and Hemodynamic Performance of 19-mm Bioprostheses Following Aortic Valve Replacement

— A Single-Institution 10-Year Experience —

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Background: Data on the clinical outcomes and hemodynamic performance of the smallest commercially available bioprostheses (19 mm) in Japan for aortic valve replacement (AVR) remain limited.

Methods and Results: We analyzed the data of 187 adults (median age, 76 [interquartile range (IQR): 73–80] years; 165 women [88%]; median follow-up, 65 [IQR: 32–95] months) with symptomatic aortic valve stenosis, regurgitation, and valve deterioration who underwent surgical AVR between January 2015 and July 2024 with the Avalus (n=7), Magna (n=77), Epic (n=26), Inspiris (n=58), or Mosaic (n=27) bioprosthesis because of having small aortic annuli. The primary and secondary endpoints were all-cause death and major adverse cardiac events, respectively. Moderate-to-severe prosthesis-patient mismatch occurred in 53 patients (28%). The overall survival rates (95% confidence interval [CI]) at 1, 3, and 5 years after valve replacement were 93.0% (88.3–95.9%), 87.0% (81.0–91.2%), and 85.7% (79.5–90.1%), respectively. The rates of freedom from major adverse cardiac and cerebrovascular events (95% CI) at 1, 3, and 5 years were 96.2% (92.1–98.2%), 90.2(84.5–93.9%), and 88.7(82.5–92.7%), respectively. Four patients required re-intervention (3, re-AVR and 1, medication). No significant differences were observed in either outcomes or hemodynamics among the different aortic bioprostheses.

Conclusions: Surgical replacement with 19-mm third-generation aortic valve bioprostheses for small aortic annuli is feasible with favorable early and mid-term hemodynamics.

Key Words: Aortic valve replacement; Bioprosthesis; Small aortic annulus

Surgical aortic valve replacement (SAVR) is still a treatment option for aortic valve diseases, including aortic stenosis (AS), aortic regurgitation (AR), and valve deterioration, with improved outcomes in recent years for patients younger than 80 years old. However, SAVR for patients with a small aortic annulus (SAA) remains challenging for surgeons because of the risk of impaired valvular hemodynamic performance and associated adverse cardiovascular clinical outcomes after small valve implantation.[1] This is a high-risk factor for prosthesis-patient mismatch (PPM) owing to the limited selection of valve size and inability to maximize the effective orifice area.[1–4]

In the clinical setting, the optimal surgical strategy for patients with SAA remains undetermined, and no clear consensus of guideline recommendations is available.[4–6] In the modern era, aortic root enlargement techniques, such as the Y-incision procedure, have been performed to implant larger valves.[7,8] Alongside established techniques, including those by Nicks and Manouguean, these new techniques for aortic root enlargement easily stabilize postoperative hemodynamic performance and develop surgical strategies in this population.[9] However, these techniques may not be suitable for all patients because of longer cardiac arrest times and increased bleeding risk compared to standard AVR.

Despite developments, data on the clinical outcomes and hemodynamic performance of the smallest commercially available surgical bioprostheses (19 mm) remain limited. To address this gap, in this study we aimed to analyze

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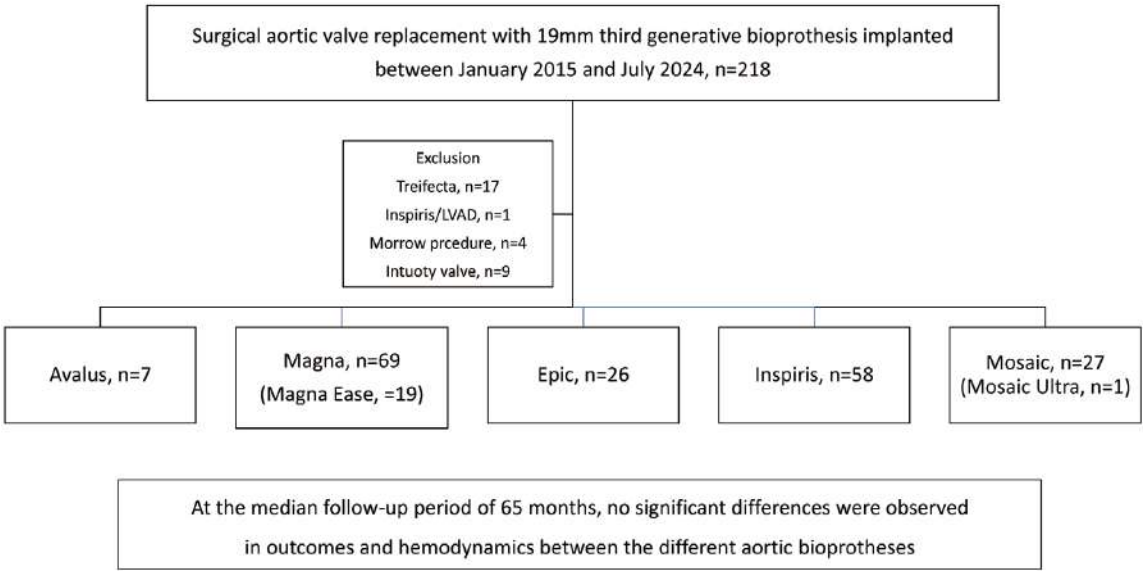

Central Figure

the clinical outcomes after 19-mm bioprosthesis AVR and report the results using echocardiographic findings. The novelty of this study lies in its focus on long-term outcomes of 5 different 19-mm bioprostheses, providing real-world evidence in a population at high risk of SAA and PPM.

Methods

Study Design and Follow-up

This single-center retrospective study was conducted in accordance with the principles of the Declaration of Helsinki (1964 and subsequent amendments) and was approved by the Institutional Ethics Committee of the Saitama Medical University International Medical Center, Japan (reference no. F25-004). The requirement for informed consent was waived owing to the retrospective nature of this study.

Hospital records were screened to identify patients treated between January 2015 and July 2024 who underwent SAVR with a 19-mm bioprosthesis. Patients were categorized into 5 groups according to the implanted 19-mm bioprosthesis model: Avalus or Mosaic (Medtronic, Minneapolis, MN, USA), Epic (Abbott Cardiovascular Inc., St. Paul, MN, USA), and Inspiris or Magna (Edwards Lifesciences, Irvine, CA, USA). Procedures were performed either electively (during elective admission) or urgently (during admission for heart failure). Patients aged ≤18 years and those who underwent a concomitant Morrow's procedure, received a Trifecta supra-annular bovine pericardial stented bioprosthesis, or underwent isolated left ventricular assist device implantation were excluded (**Figure 1**). The retrospective review of the clinical course of each patient was based on patient charts, including preoperative, postoperative (intensive care unit), and discharge assessments. Follow-up data on clinical status and transthoracic echocardiography were obtained from the patients' general practitioners or private cardiologists by telephone and fax communication and were complete for 100% of patients. The clinical follow-up was closed on November 30, 2024, when the last enrolled patient completed 3 months of follow-up. The primary endpoint was all-cause death after SAVR. The secondary endpoint was the first rehospitalization for cardiac events requiring reintervention because of valve deterioration. Rehospitalization was defined as new-onset or worsening signs and symptoms of heart failure that required urgent therapy and resulted in hospitalization. Anticoagulation management and anti-infective therapy were routinely administered.[10] Echocardiographic measurements were performed according to current recommendations.[11] The incidence of PPM was calculated following standard guidelines: not clinically significant (indexed effective orifice area [iEOA]: >1 cm^2/m^2), mild (iEOA: <1 and >0.85 cm^2/m^2), moderate (iEOA: <0.85 and >0.65 cm^2/m^2), and severe (iEOA: <0.65 cm^2/m^2).[12] Structural valve deterioration was defined according to the statements of the European Association of Cardio-Thoracic Surgery/European Association of Percutaneous Cardiovascular Interventions, Valve-in-Valve International Database, and Valve Academic Research Consortium-3, based on the identification of morphological and hemodynamic valve deterioration of aortic bioprosthetic valves at echocardiographic follow-up.[13–15]

Surgical Procedures

Experienced board-certified cardiovascular surgeons performed all procedures via a median sternotomy or right thoracotomy. The selection of implanted valve was decided by each surgeon. SAVR with concomitant procedures, including mitral valve repair or replacement, tricuspid valve repair (TVR), coronary artery bypass grafting, pulmonary vein ablation, and other procedures (atrial septal defect [ASD] closure and resection of the left atrial appendage), was performed via full sternotomy whenever possible. With sternotomy, cardiopulmonary bypass (CPB) was established through direct cannulation of the ascending aorta and right atrial vein or superior vena cava/inferior vena cava in patients requiring TVR and ASD closure.

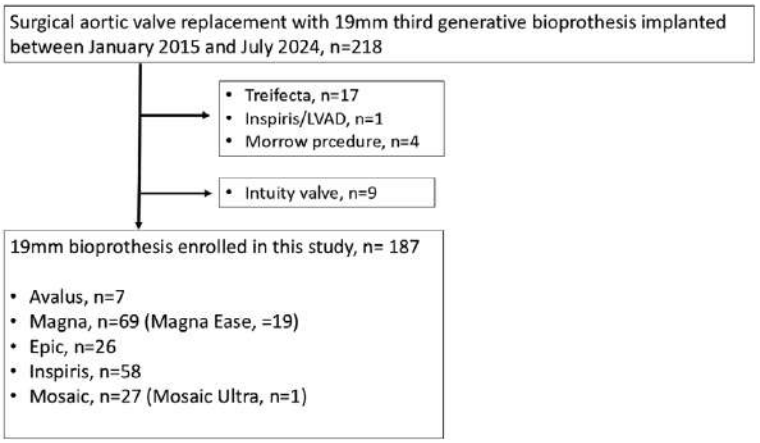

Figure 1. Flow chart for selection of patients.

Table 1. Pastients' Baseline Characteristics According to 19-mm Bioprosthesis Used for AVR

	All (n=187)	Avalus (n=7)	Epic (n=26)	Inspiris (n=58)	Magna (n=69)	Mosaic (n=27)	P value
Age, IQR (years)	76 (73–80)	77 (75–80)	78 (74–80)	76 (72–80)	76 (72–81)	76 (71–80)	0.93
Female sex	165 (88)	4 (57)	23 (88)	53 (91)	60 (87)	25 (93)	0.17
BMI, IQR (kg/m^2)	22 (20–25)	18 (18–21)	22 (19–23)	23 (20–25)	22 (21–24)	24 (21–26)	0.07
BSA, IQR (m^2)	1.40 (1.32–1.5)	1.29 (1.27–1.42)	1.40 (1.32–1.49)	1.44 (1.33–1.53)	1.39 (1.32–1.49)	1.4 (1.3–1.49)	0.31
Arterial hypertension	125 (67)	5 (71)	19 (73)	35 (60)	46 (67)	20 (74)	0.71
Diabetes mellitus	51 (27)	2 (29)	6 (23)	16 (28)	18 (26)	9 (33)	0.93
Hyperlipidemia	50 (27)	4 (57)	2 (7.7)	20 (34)	17 (25)	7 (26)	0.030
Peripheral artery disease	9 (4.8)	0 (0)	0 (0)	0 (0)	6 (8.7)	3 (11)	0.041
Prior PCI	19 (10)	0 (0)	4 (15)	2 (3.4)	8 (12)	5 (19)	0.13
Use of steroids	11 (5.9)	0 (0)	2 (7.7)	2 (3.4)	4 (5.8)	3 (11)	0.63
Hemodialysis	32 (17)	1 (14)	7 (27)	8 (14)	12 (17)	4 (15)	0.67
Prior stroke	24 (13)	0 (0)	2 (7.7)	8 (14)	8 (12)	6 (22)	0.54
Atrial fibrillation	48 (26)	1 (14)	9 (35)	11 (19)	18 (26)	9 (33)	0.45
Laboratory data							
Aspartate aminotransferase, IQR (IU/L)	23 (18–28)	23 (21–26)	21 (17–26)	24 (20–29)	23 (18–28)	23 (18–30)	0.73
Alanine aminotransferase, IQR (IU/L)	15 (11–19)	17 (15–20)	16 (10–17)	16 (12–23)	15 (10–18)	15 (10–21)	0.17
Blood urea nitrogen, IQR (mg/dL)	20 (15–30)	20 (17–26)	21 (17–31)	19 (14–24)	20 (16–30)	18 (14–31)	0.49
Creatinine, IQR (mg/dL)	0.8 (0.63–1.47)	0.84 (0.64–0.97)	0.99 (0.72–3.30)	0.72 (0.57–1.11)	0.85 (0.63–1.67)	0.71 (0.60–1.23)	0.084
eGFR, IQR (mL/min/1.73 m^2)	54 (29–72)	61 (52–70)	42 (11–59)	60 (44–79)	52 (23–69)	61 (34–74)	0.052
CRP, IQR (mg/dL)	0.10 (0.041–0.38)	0.16 (0.081–1.64)	0.082 (0.048–59)	0.097 (0.040–0.29)	0.081 (0.036–0.46)	0.26 (0.88–1.10)	0.094

Data are n (%) if not otherwise specified. AVR, aortic valve replacement; BMI, body mass index; BSA, body surface area; CRP, C-reactive protein; eGFR, estimated glomerular filtration rate; IQR, interquatile range; PCI, percutaneous coronary intervention.

Access to the mitral valve was gained via either a direct left atrial or transseptal incision, depending on the need for TVR and ASD closure. Standard SAVR was performed on the arrested heart at normal temperature (36°C). Intraoperative transesophageal echocardiography (TTE) was performed to verify the absence of trans- or paravalvular regurgitation during AV replacement. All patients were treated with warfarin for anticoagulation therapy for 3 postoperative months.

Statistical Analysis

Data are expressed as mean±standard deviation or median (range and/or interquartile range [IQR]) for continuous variables and frequencies (percentages) for categorical variables. Baseline characteristics, echocardiography findings, and clinical outcomes of the patients in the 5 groups were compared using the analysis of variance test for continuous, normally distributed data. Fisher's exact test was used to compare categorical variables. The Friedman test

Table 2. Baseline Transthoracic Echocardiography in Patients Undergoing AVR With 19-mm Bioprostheses

	All (n=187)	Avalus (n=7)	Epic (n=26)	Inspiris (n=58)	Magna (n=69)	Mosaic (n=27)	P value
Echocardiography							
LV ejection fraction, IQR (%)	66 (49–76)	68 (50–74)	72 (57–80)	62 (47–76)	66 (54–74)	61 (49–75)	0.41
Aortic valve area, IQR (cm^2)	0.71 (0.60–0.87)	1 (0.74–1.09)	0.74 (0.64–0.95)	0.68 (0.59–0.81)	0.75 (0.61–0.85)	0.7 (0.57–0.8)	0.23
Mean pressure gradient, IQR (mmHg)	43 (34–57)	31 (25–41)	42 (34–59)	44 (37–62)	42 (34–54)	43 (36–52)	0.24
LV diastolic diameter, IQR (mm)	45 (41–50)	45 (45–50)	45 (41–51)	46 (41–52)	44 (41–49)	46 (42–50)	0.60
LV systolic diameter, IQR (mm)	28 (28–34)	28 (25–35)	25 (22–30)	28 (24–36)	28 (23–32)	29 (22–36)	0.50
Interventricular septum thickness, IQR (mm)	12 (10–14)	10 (10–12)	12 (11–14)	12 (10–14)	11 (11–13)	12 (12–14)	0.38
Posterior wall thickness, IQR (mm)	11 (10–13)	10 (9.5–12)	11 (10–13)	11 (10–13)	11 (10–12)	12 (11–13)	0.37
Annulus diameter, IQR (mm)	21 (20–21)	20 (20–21)	21 (20–21)	21 (20–22)	21 (20–22)	20 (19–21)	0.25
Deceleration time, IQR (ms)	234 (185–293)	215 (194–325)	215 (171–244)	224 (171–288)	259 (203–316)	233 (192–268)	0.14
LV outflow tract							
Peak velocity, IQR (m/s)	1 (0.80–1.2)	1.0 (0.90–1.2)	1.1 (0.90–1.2)	1.0 (0.90–1.1)	0.9 (0.8–1.2)	1.0 (0.75–1.1)	0.36
Peak pressure gradient, IQR (mmHg)	4 (2.6–5.4)	4.0 (3.2–5.1)	4.8 (3.0–5.8)	4 (3.2–4.8)	3.2 (2.6–5.8)	3.8 (2.25–4.8)	0.41
Velocity time integral, IQR (cm)	23 (19–27)	22 (20–22)	24 (20–30)	24 (20–25)	22 (18–28)	21 (18–25)	0.64
LV outflow tract diameter, IQR (mm)	20 (19–21)	21 (20–22)	20 (19–20)	20 (19–21)	20 (19–21)	20 (19–20)	0.34
LV cardiac output, IQR (L/min)	5 (4.3–5.7)	5.5 (5.1–5.8)	4.8 (4.4–5.7)	5.1 (4.8–5.8)	4.8 (3.9–5.7)	4.7 (3.9–5.3)	0.19
Pathology of AV							0.079
Regurgitation	22 (12)	0 (0)	5 (19)	10 (17)	6 (8.7)	1 (3.7)	
Stenosis	154 (82)	7 (100)	17 (65)	44 (76)	62 (90)	24 (89)	
Stenosis and regurgitation	10 (5.3)	0 (0)	4 (15)	3 (5.2)	1 (1.4)	2 (7.4)	
Infective endocarditis	1 (0.53)	0 (0)	0 (0)	1 (1.7)	0 (0)	0 (0)	

Data are n (%) if not otherwise specified. AV, aortic valve; AVR, AV replacement; IQR, interquatile range; LV, left ventricular.

was used to compare non-parametric continuous data between groups. Survival was determined using the Kaplan-Meier method, and comparisons were made using the log-rank test. The differences between any 2 of the 5 groups were assessed using Holm's test. Statistical significance was set at $P<0.05$. All reported P values were two-sided. Statistical analyses were performed using SPSS for Windows (version 22.0; IBM Japan, Tokyo, Japan).

Results

Study Population

Between January 2015 and July 2024, 218 patients underwent SAVR with 19-mm bioprostheses for various aortic valve disease pathologies. Of them, 187 (86%) who underwent SAVR with a third-generation bioprosthesis (Avalus, n=7; Magna, n=69; Epic, n=26; Inspiris, n=58; and Mosaic, n=27) were enrolled in this study (**Figure 1**). Baseline characteristics of the study population are summarized in **Table 1**. The median patient age was 76 (IQR: 73–80) years, and 88.2% were women. Body surface area and body mass index values were not significantly different among the 5 groups (P=0.31 and 0.07, respectively). At the time of SAVR, a large number of patients (n=154, 82.3%) had operative indications due to AS, but only 1 patient had an indication because of infective endocarditis (**Table 2**). Preoperative echocardiography showed no differences among the 5 groups in left ventricular ejection fraction (LVEF), aortic valve area (AVA), mean aortic valve pressure gradient, or any of the parameters measured at the level of the aortic valve annulus and left ventricular outflow tract. The median aortic valve annulus diameter measured 21 mm (IQR: 20–21) preoperatively (**Tables 1**,**2**).

Perioperative Outcomes

Isolated AVR was performed in 85 patients, and 102 patients underwent additional procedures including coronary artery bypass grafting and other valve surgeries. There were 7 inhospital deaths (3.7%): 3 died of cardiac events (low output syndrome [LOS]), 2 of whom were diagnosed with AS with terminal heart failure and underwent replacement with Magna and Mosaic valves, respectively. Although intra-aortic balloon pump was properly used, the 2 patients died of LOS within 1 week after surgery. The other patient had a history of SAVR with a mechanical valve. During the preoperative phase, extracorporeal membrane oxygenation was administered because of circulatory failure caused by valve-related thrombosis following valve obstruction. Emergency surgical replacement with a Mosaic valve was performed, but the patient died of LOS within 24 h of surgery. The other 4 patients died of pneumonia within 1 month after SAVR. In total, 139 perioperative survivors were discharged, and the remaining 41 survivors were transferred to a rehabilitation hospital with a median intensive care unit stay of 5 days (IQR: 3–8 days) and a hospital stay of 17 days (IQR: 14–28 days) (**Table 3**).

Table 3. Procedural Characteristics and Early Outcomes of Patients Undergoing AVR With 19-mm Bioprosthesis

	All (n=187)
Elective surgery	102 (55)
Full sternotomy	187 (100)
Redo surgery	19 (10)
Isolated aortic valve replacement	85 (45)
Concomitant procedure	
Mitral valve surgery	14 (7.5)
Mitral and tricuspid valve surgery	15 (8.0)
Tricuspid valve surgery	6 (3.2)
Coronary bypass grafting	48 (26)
Other	19 (10)
Early outcomes	
Intubation <24 h	133 (71)
Re-intubation	8 (4.3)
Intensive care unit stay, IQR (days)	5 (3–8)
Hospital stay, IQR (days)	17 (14–28)
In-hospital death	7 (3.7)
At discharge	
Home	139 (74)
Rehabilitation	41 (22)
Paravalvular leakage	1 (0.53)
Pacemaker implantation	4 (2.1)

Data are n (%) if not otherwise specified. AVR, aortic valve replacement; IQR, interquatile range.

Later Clinical Outcomes and Survival

The median follow-up period was 65 months (IQR: 32–95 months) and follow-up data were available for all patients. Kaplan-Meier overall survival analysis at 1, 3, and 5 years after AVR showed 93.0% (95% CI; 88.3–95.9%), 87.0% (95% CI; 81.0–91.2%), and 85.7% (95% CI; 79.5–90.1%), respectively (**Figure 2A**). Kaplan-Meier freedom from major adverse cardiac and cerebrovascular events (MACCE) analysis at 1, 3, and 5 years showed 96.2% (95% CI; 92.1–98.2%), 90.2% (95% CI; 84.5–93.9%), and 88.7% (95% CI; 82.5–92.7%), respectively (**Figure 2B**). During the follow-up period, 28 patients died: 3 from cardiac events, and 25 from non-cardiac events. Kaplan-Meier freedom from re-intervention analysis at 3 and 5 years showed 98.6% (95% CI; 94.5–99.6%) and 97.8% (95% CI; 93.2–99.3%), respectively (**Figure 2C**). A total of 4 patients required re-intervention for the implanted bioprosthesis. Of them, 3 patients required redo AVR: 1 patient underwent redo AVR with a Magna valve 28 months after AVR due to valve stenosis with an implanted Epic valve; 1 patient underwent redo AVR with a Magna valve 27 months after AVR because of deterioration of the implanted Magna valve; 1 patient underwent repeat AVR with an Epic valve 52 months after surgery because of stenosis of the implanted Mosaic valve. The 4th patient with a Mosaic valve had heart failure with a high gradient pressure 104 months after surgery, and he chose medication because of his advanced age. According to the Kaplan-Meier analysis of overall survival, freedom from MACCE, and freedom from re-intervention for bioprostheses, categorized by bioprosthesis type, no significant differences were observed among the 5 bioprosthesis groups (**Figure 3A–C**).

Hemodynamic Comparison of Implanted Valves

According to the PPM classification, 53 patients (28%) were classified as having moderate (n=49) or severe PPM (n=4) on postoperative echocardiography. The PPM classification at discharge was not statistically different among the 5 groups (P=0.404). Echocardiographic data are summarized in **Table 4**. LVEF and AVA values were not significantly different at any point, including at discharge and 1 and 3 years after AVR, among the 5 groups. The mean aortic valve pressure gradient values appeared to differ among the 5 groups, with a trend toward being lower with the Avalus valve. However, pressure gradients were within the normal range for all groups.

Discussion

In this study, we analyzed clinical outcomes after SAVR using 5 types of 19-mm labelled bioprosthetic valves. The

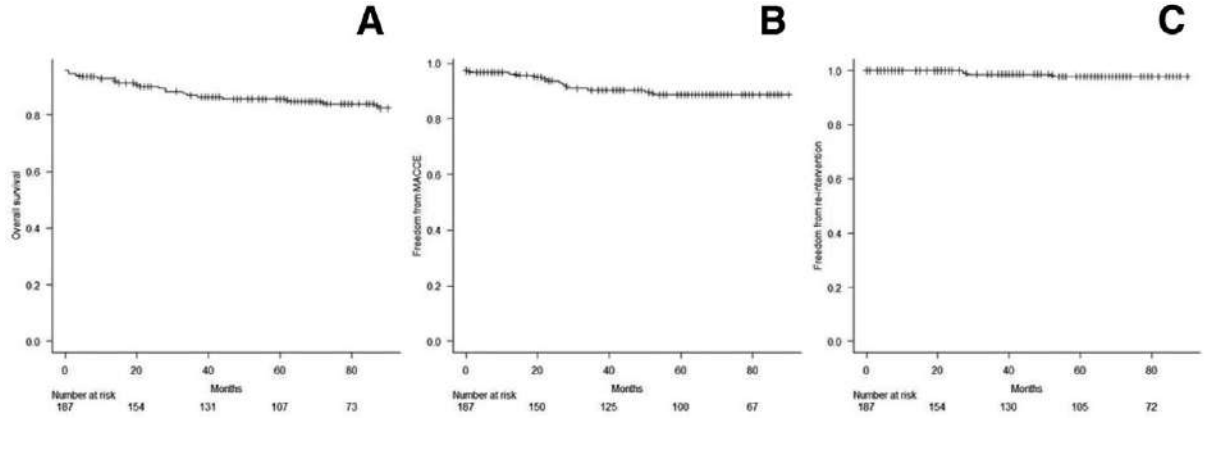

Figure 2. Clinical outcomes of the full cohort. Kaplan-Meier curves for (**A**) overall survival, (**B**) freedom from major adverse cardiac and cerebrovascular events (MACCE), and (**C**) rehospitalization.

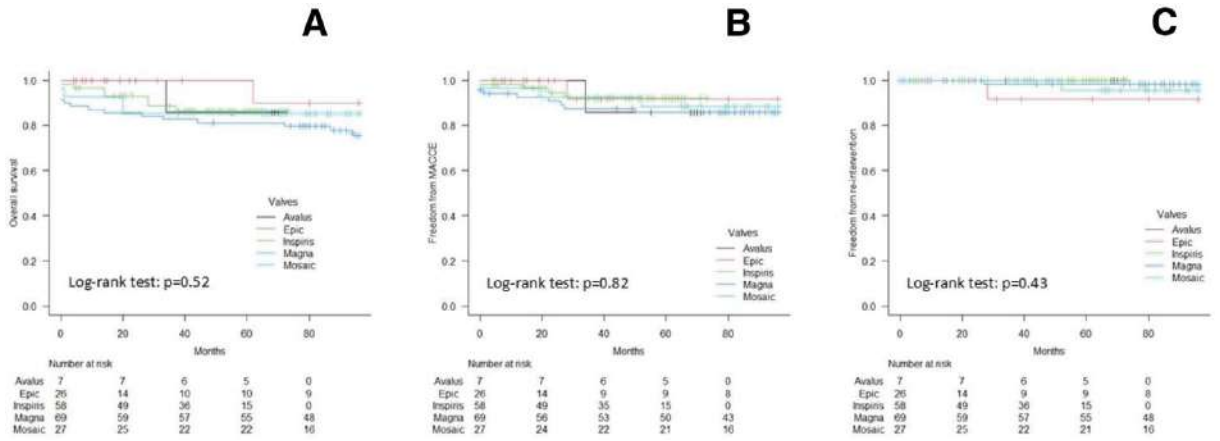

Figure 3. Clinical outcomes classified by 5 types of valves. Kaplan-Meier curves for (**A**) overall survival, (**B**) freedom from major adverse cardiac and cerebrovascular events (MACCE), and (**C**) rehospitalization, show no significant difference during the study period (log-rank test, P=0.523, P=0.816, and P=0.428, respectively).

Table 4. Comparison of Echocardiography Results for the Implanted 19-mm Bioprostheses

	Avalus (n=7)	Epic (n=26)	Inspiris (n=58)	Magna (n=69)	Mosaic (n=27)	P value
Effective orifice area index at discharge, IQR (cm^2/m^2)	1.05 (0.83–1.19)	0.90 (0.80–0.99)	0.96 (0.82–1.15)	0.92 (0.81–1.03)	0.87 (0.76–0.96)	0.404
Left ventricular ejection fraction, IQR (%)						
At discharge	67 (50–74)	65 (53–73)	59 (51–74)	66 (57–74)	66 (52–73)	0.54
1 year	71 (66–78)	71 (68–76)	69 (60–77)	71 (62–78)	70 (59–75)	0.93
3 years	64 (58–70)	65 (62–77)	67 (60–76)	72 (65–79)	70 (66–73)	0.55
	0.11	0.12	0.19	0.029	0.0077	
Mean pressure gradient, IQR (mmHg)						
At discharge	20 (16–22)	17 (13–21)	14 (11–16)	15 (13–20)	19 (14–24)	0.0033
1 year	14 (12–14)	18 (14–23)	15 (13–19)	14 (12–17)	19 (17–25)	<0.005
3 years	10 (10–11)	18 (15–20)	15 (13–21)	15 (13–19)	23 (21–27)	<0.005
	0.174	0.31	0.064	0.19	0.66	
Aortic valve area, IQR (cm^2)						
At discharge	1.33 (1.12–1.58)	1.30 (1.1–1.36)	1.38 (1.2–1.62)	1.32 (1.2–1.5)	1.22 (1.09–1.40)	0.10
1 year	1.16 (1.09–1.25)	1.31 (1.19–1.40)	1.34 (1.1–1.5)	1.3 (1.15–1.41)	1.26 (1.1–1.38)	0.62
3 years	1.21 (1.13–1.22)	1.24 (1.2–1.37)	1.2 (1.08–1.4)	1.36 (1.22–1.56)	1.19 (0.96–1.41)	0.10
	0.72	0.31	0.14	0.13	0.42	

The number of enrolled patients in each group at follow-up was: At 1 year: Avalus=6; Epic=20; Inspiris=52; Magna=58; Mosaic=21; At 3 years: Avalus=5; Epic=18; Inspiris=46; Magna=48; Mosaic=13. IQR, interquartile range.

operative outcomes were acceptable, and the hemodynamics of all valve types remained stable at a median follow-up of 5 years.

In the clinical setting, female sex is well known to be a higher risk factor for SAA.[16] In addition to being female, older Japanese patients who require AVR often have an SAA relative to their body size and typically require smaller prostheses than Western patients.[17,18] In the present study, the proportion of female patients was high (88.2%), with a median age of 76 years, compared to other studies.[6,19] In the modern era, aortic root enlargement (i.e., using the Y-incision) has been performed to allow implantation of larger aortic valves, and many surgeons support this approach.[6–8] Such surgical remodeling of the aortic root may result in more effective hemodynamics after SAVR with larger valve sizes. However, as the dimensions of the aortic root (including the coronary artery ostium) can change, the long-term outcomes of these strategies remain unclear.[20] Additionally, patients with aortic wall fragility (i.e., collagen disease and inflammation) or severe calcification may have a high risk of severe complications (i.e., surgical bleeding, rupture, and pseudo-rupture). Further

prospective multicenter studies with larger cohorts are warranted to investigate this clinically essential and underrepresented topic.

PPM is well known as an important parameter for determining the optimal valve size to obtain a suitable cardiac output.[2] In this study, 4 patients (Magna, n=2; Inspiris, n=1; Epic, n=1) had severe PPM, which was associated with MACCE, although none of patients needed re-intervention. Of them, 3 were alive at the 4-, 79-, and 82-month follow-ups, and 1 died of malignancy at 37 months of follow-up. For the 3 associated valves, the labelled diameters do not correspond precisely to the inflow orifice diameter, and the definition of the labelled valve size differs among the manufacturers.[21] Therefore, when selecting an appropriate valve based on anatomical dimensions, it is essential to estimate the size discrepancy with the labelled diameters, inlet orifice diameter, and outlet orifice diameter for all models.[22] The inlet and outlet orifice diameters of the Avalus valve were equal, in contrast to the other valves. As such, the area of the Avalus valve may be larger than that of other valves. In this study, because of the limited number of patients receiving the Avalus valve (n=7), the LVEF and AVA values may not have differed among the groups. Further accumulation of cases and evidence, including mid- to long-term results and echocardiographic data, is required.

In older patients with severe AS, TAVR has become an effective alternative to SAVR owing to its minimally invasive nature. According to a recent randomized clinical trial, no significant differences in clinical outcomes at the 2-year follow-up were observed between SAVR and TAVR in patients with severe AS and an SAA.[23] In our study, 4 patients had valve deterioration with heart failure secondary to a higher valve pressure gradient: 3 underwent repeat SAVR with a 19-mm bioprosthesis, and 1 requested medication. The 3 patients who underwent redo SAVR survived without recurrent heart failure. In the modern era of minimally invasive transcatheter treatment, transcatheter valves-in-valves (ViV-TAVR) has been gradually developed.[24,25] An aggressive strategy with ViV-TAVR has been attempted worldwide, and some authors support the superiority of postprocedural outcomes over redo SVR.[24] However, outcome comparisons between SAVR and ViV-TAVR in patients previously treated with a 19-mm labelled bioprosthesis remain controversial. Further large-scale studies with long-term follow-up are warranted to gain a deeper understanding of this issue. The durability and hemodynamic performance of the 19-mm valves in this study were acceptable. In cases of failed SAVR with a 19-mm bioprosthesis (i.e., valve deterioration), redo surgery remains the first-choice treatment.

Study Limitations

Primarily, this was a non-randomized, retrospective, single-center, observational study with a limited number of patients. Because of this design, the selection of valve model was at the surgeon's discretion. Furthermore, isolated AVR was performed in only 45% of the enrolled patients. Therefore, the association between aortic valve characteristics and postoperative LV function was not directly assessed. Moreover, all TTE data were evaluated by experienced cardiologists but were not reviewed by an independent core laboratory. Thus, the conclusions of this study should be interpreted with caution until confirmation in prospective, randomized clinical trials.

Conclusions

In this study, the operative outcomes were acceptable, and hemodynamics were stable at a median follow-up of 5 years. The outcomes did not differ among the 5 19-mm bioprosthesis models evaluated and the findings suggest that 19-mm third-generation bioprostheses can provide satisfactory mid-term results in small-annulus patients when annular enlargement is not feasible.

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Disclosures

The authors declare no conflicts of interest. This single-center study was conducted in accordance with the principles of the Declaration of Helsinki (1964) and its subsequent amendments and was approved by the Institutional Ethics Committee of the Saitama Medical University International Medical Center, Japan (approval no. F25-004).

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None.

Author Contributions

T.G.: data collection, analysis, and draft writing; Y. Kanazawa: data collection; Y. Kumagai: data collection; Y.G.: data collection; T. Akatsu: supervision; T. Arai: supervision; S.N.: supervision; A.Y.: supervision.

Data Availability Statement

The deidentified participant data will be shared on a request basis. Please directly contact the corresponding author to request data sharing.

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