Transcatheter Aortic Valve Implantation for Degenerated 19-mm Aortic Bioprosthetic Valve

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Background: The valve-in-valve procedure, in which a transcatheter heart valve (THV) is implanted over a prosthetic valve, has been shown to be safe and therapeutically effective, depending on the size of the replacement valve.

Methods and Results: We report 3 cases of successful valve-in-valve procedure to replace a degenerated 19-mm stented prosthetic aortic valve. Balloon-expanding THVs were implanted: 20-mm in the 1st case and 23-mm in the next 2. Aortic stenosis was almost completely resolved in all patients, who recovered promptly and without cardiac adverse events.

Conclusions: Using the valve-in-valve procedure for a 19-mm degenerated bioprosthesis was feasible and safe.

Key Words: Degenerated bioprosthesis; Transcatheter aortic valve implantation; Valve-in-valve

Although redo valve replacement is the standard intervention for a degenerated aortic bioprosthetic valve,^{1,2} mortality associated with repeat valve replacement has been reported as 11–32% in selected high-risk patients.^{3,4} Transcatheter aortic valve replacement for a degenerated aortic bioprosthetic valve, also known as a “valve-in-valve” procedure, has been reported by the global Valve-in-Valve International Data (VIVID) Registry as safe and effective.⁵ In that report, Dvir et al showed that a small implanted surgical valve (labeled size ≤ 21 mm) was an independent risk factor for 1-year mortality after valve-in-valve. Importantly, valve-in-valve mortality associated with the 19-mm surgical valve was 2.4% in the VIVID Registry, although in Japan, the 19-mm surgical valve is used in 18.7–49.8% of all aortic valve replacement procedures.^{6,7} The VIVID Registry report therefore suggested that, although valve-in-valve for a small-sized bioprosthetic valve is challenging, it is clinically necessary for Japanese patients. We report the first 3 clinical cases of valve-in-valve in patients with a degenerated 19-mm aortic bioprosthesis.

Methods

The National Cerebral and Cardiovascular Center Institutional Review Board approved the study (UMIN000026450),

a prospective, interventional cohort study with off-label use of a commercially available transcatheter heart valve (THV) in Japan for a degenerated bioprosthesis. The primary endpoint was safety and therapeutic efficacy within 30 days, based on Valve Academic Research Consortium-2.⁸ Between December 2016 and March 2017, 3 patients with a 19-mm bioprosthesis underwent valve-in-valve with a SAPIEN XT Transcatheter Heart Valve (Edwards Lifesciences, Irvine, CA, USA). Baseline demographics and clinical outcomes are shown in the **Table**. Deployment was performed with nominal volume, and pre- or post-dilatation was not performed. Standard transthoracic echocardiography was used to assess heart and valve function at baseline and on postoperative day 5.

Patient 1

An 82-year-old woman presented with progressive congestive cardiac failure caused by structural valve deterioration (SVD) of a 19-mm Carpentier-Edwards PERIMOUNT Aortic Heart Valve implanted 12 years earlier. Echocardiography showed a severely stenotic aortic valve with global thickening and partial calcification of all 3 leaflets. Surgical redo replacement was deferred because of a “porcelain” aorta, but a 20-mm SAPIEN XT (Edwards Lifesciences) was successfully implanted over the previously implanted

Received August 10, 2017; revised manuscript received October 4, 2017; accepted October 22, 2017; released online November 11, 2017 Time for primary review: 25 days

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Table. Patients' Baseline Characteristics and Clinical Outcomes of Valve-in Valve Procedure

	Patient 1	Patient 2	Patient 3
Age at valve-in-valve (years)	82	82	77
Sex	F	F	F
BSA (m ²)	1.33	1.15	1.56
STS PROM (%)	6.7	5	4.4
Baseline NYHA class	II	II	II
Prosthesis previously implanted	PERIMOUNT	Mosaic	PERIMOUNT
Prosthesis true internal diameter	17	15.5	17
Mode of degeneration	Stenosis	Stenosis and regurgitation	Stenosis
Interval from SAVR (years)	12.7	6.7	11.3
Baseline max aortic gradient (mmHg)	72	98	96
Baseline mean aortic gradient (mmHg)	39	53	56
Baseline indexed effective orifice area (cm ² /m ²)	0.81	0.52	0.53
Baseline LVEF (%)	61	60	33
Valve area calculated by MDCT (mm ²)	180.6	216.6	160.8
Perimeter calculated by MDCT (mm)	49.5	53.0	45.8
Mean sinus of Valsalva height calculated by MDCT (mm)	15.0	15.5	18.2
Mean sinus of Valsalva diameter calculated by MDCT (mm)	26.7	28.9	26.7
Left coronary ostia height calculated by MDCT (mm)	9.6	9.5	9.5
Right coronary ostia height calculated by MDCT (mm)	12.8	16.8	16.7
Most relevant risk factor	Porcelain aorta	Frailty	Impaired LV function
Access for valve-in-valve	Transfemoral	Transfemoral	Transfemoral
Transcatheter heart valve	SAPIEN XT	SAPIEN XT	SAPIEN XT
Transcatheter heart valve size (mm)	20	23	23
Postprocedural max. aortic gradient (mmHg)	51	25	41
Postprocedural mean aortic gradient (mmHg)	35	16	29
Indexed effective orifice area (cm ² /m ²)	0.78	0.95	0.86
LVEF (%)	65	49	60
Oversizing ratio of THV-bioprostheses (%)	74	108	158
Prosthetic valve regurgitation	None	None	None
Paravalvular regurgitation	None	None	None
Procedural complications	None	None	None
Length of postoperative hospital stay (days)	6	6	6
NYHA class at discharge	II	I	I

LVEF, left ventricular ejection fraction; MDCT, multidetector computed tomography; NYHA, New York Heart Association; SAVR, surgical aortic valve replacement; STS PROM, Society of Thoracic Surgeon Predicted Risk of Mortality.

valve via a transfemoral approach (**Figure**).

Patient 2

An 82-year-old woman presented with acute congestive cardiac failure caused by SVD of a 19-mm Mosaic™ Bioprosthesis (Medtronic Inc., Corona, CA, USA) aortic valve, which had been implanted 6 years earlier, concomitant with implantation of a 25-mm Mosaic™ (Medtronic Inc.) mitral valve for severe aortic stenosis and severe mitral regurgitation. Echocardiography showed severe stenosis and moderate insufficiency of the aortic prosthetic valve and normal function of the mitral prosthetic valve. Surgical redo replacement was deferred because of the patient's frailty, but a 23-mm SAPIEN XT (Edwards Lifesciences) was successfully implanted over the previous bioprosthesis via a transfemoral approach (**Figure**).

Patient 3

A 77-year-old woman presented with progressive congestive cardiac failure caused by SVD of a 19-mm Carpentier-Edwards PERIMOUNT Aortic Heart Valve (Edwards

Lifesciences), which had been implanted 11 years earlier to treat severe aortic stenosis associated with a bicuspid aortic valve. Echocardiography showed severe stenosis of the prosthetic valve, with global thickening and partial calcification of all 3 leaflets. Surgical redo replacement was deferred because of impaired left ventricular function, but a 23-mm SAPIEN XT (Edwards Lifesciences) was successfully implanted over the previously implanted valve via a transfemoral approach (**Figure**).

Results

There were no procedural complications. All patients recovered promptly. Echocardiography demonstrated a substantially reduced pressure gradient across the aortic valve, with no valvular insufficiency or paravalvular leakage in any patient. Patients were free of symptoms related to cardiac failure at the latest follow-up, which was on day 200, 110, and 123 in patients 1, 2, and 3, respectively.

Figure. Perioperative fluoroscopy of the valve-in-valve procedure shows a 20-mm SAPIEN XT Transcatheter Heart Valve in patient 1 and a 23-mm SAPIEN XT Transcatheter Heart Valve in patients 2 and 3. Fluoroscopy of the original implanted surgical valve shows (A) the stent frame, (B) the deployment level before the valve-in-valve procedure, (C) at deployment and (D) after the valve-in-valve procedure.

Discussion

The challenges in valve-in-valve treatment for a degenerated 19-mm bioprosthetic valve are optimization of the deployment position and the type and size of the THV. Dvir et al⁵ reported that, in valve-in-valve, the aortic pressure gradient is more reduced with a self-expanding device than with a balloon-expanding device. However, there was no significant difference in the 1-year mortality between the 2 THV types.

More importantly, this procedure can lead to valve malposition or coronary obstruction. In particular, patients with a small surgical valve often have a small Valsalva sinus or a short coronary ostium, which should be considered when selecting the THV.⁹⁻¹² The CoreValve Evolut R (Medtronic) for small, surgically treated valves should be carefully selected.¹³ Regarding the use of a balloon-expandable device, Bapat et al suggest that supra-annular implantation creates a cone-shaped THV with good functionality.⁹ To achieve appropriate deployment, the bottom level of THV implantation was deployed <20% below the

sewing ring of the surgical valve, as previously reported.⁹ Moreover, underexpansion of a balloon-expandable device in the valve-in-valve procedure for a small stented prosthesis would cause a residual gradient.¹⁴ To minimize residual aortic gradients after the valve-in-valve procedure for a small prosthesis, the 23-mm SAPIEN XT instead of the 20-mm SAPIEN XT was used for the latter 2 patients in the present cases and they showed a mean postprocedural gradient <30 mmHg, which was not significantly different from those in the previous report.⁵ Severe prosthesis-patient mismatch (defined as EOAi $\leq 0.65 \text{ cm}^2/\text{m}^2$) is associated with death.¹⁵ In the present cases, the outer expansion of the 23-mm SAPIEN XT from the stent posts of the surgical valve (Figure C-2, C-3) was associated with better hemodynamics (obtained EOAi $0.86\text{--}0.95 \text{ cm}^2/\text{m}^2$) than with the normal shape created with the 20-mm valve (Figure C-1), for which the EOAi was $0.78 \text{ cm}^2/\text{m}^2$. Thus, the type and size of the THV need to be selected according to the size and type of prosthesis and the native aortic root. Clinical follow-up with regular echocardiography is mandatory.

In conclusion, early outcomes demonstrated that the

valve-in-valve procedure using a balloon-expanding THV was feasible, safe, and therapeutically effective in high-risk patients with a degenerated stented 19-mm aortic bioprosthetic valve.

Disclosures

Devices were provided without compensation by Edwards Lifesciences and Medtronic. T.F. is an advisor to Medtronic.

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