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Case Report

Percutaneous transseptal transcatheter mitral valve-in-valve replacement for degenerated mitral bioprosthesis: The first experience in Japan

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ABSTRACT

A 76-year-old woman had received surgical mitral valve replacement with Magna Mitral Ease (Edwards Lifesciences, Irvine, CA, USA) 25 mm for functional severe mitral regurgitation 6 years previously. She presented recurrence of heart failure due to severe stenotic and moderate regurgitant degeneration of the implanted mitral bioprosthesis. Considering her comorbidities and left ventricular systolic dysfunction, our heart valve team eventually decided to perform percutaneous transseptal transcatheter mitral valve-in-valve replacement instead of surgical redo mitral valve replacement, using a 26 mm SAPIEN 3 valve (Edwards Lifesciences) via trans-femoral approach. Post-procedural course was uneventful and she was discharged on post-procedural day 2. This is, to the best of our knowledge, the first case of successful percutaneous transseptal transcatheter mitral valve-in-valve replacement in Japan. Further large-scale prospective studies are warranted to validate its long-term safety and efficacy, particularly by comparing with the redo surgery.

<**Learning objective:** We experienced an off-label transseptal mitral valve-in-valve replacement using SAPIEN 3 to treat degenerative mitral bioprosthesis for the first time in Japan. Although further large-scale prospective studies are warranted, this procedure should be a promising therapeutic alternative to conventional redo-surgery, particularly for elderly patients with multiple comorbidities.>

Introduction

Bioprosthetic mitral valve dysfunction requiring re-operation develops in approximately 20% of patients during 10 years following surgical mitral valve replacement (MVR) [1]. Given the worldwide prolonging life span, such a bioprosthesis dysfunction is of great concern. Transcatheter aortic valve-in-valve replacement for the degenerated aortic bioprosthesis is now reimbursed in Japan. On the other hand, transcatheter mitral valve-in-valve replacement (TMVR-VIV) has not yet been licensed in Japan, although such a strategy has already been popular in the USA [2].

The transapical approach is theoretically the shortest access to deliver the new bioprosthesis on the mitral position, whereas a transseptal approach has recently been preferred in real-world practice given its superiority in safety and efficacy [2]. We here report the first experience in Japan of TMVR-VIV performed via percutaneous transfemoral-transseptal approach using the SAPIEN 3 (Edwards Lifesciences, Irvine, CA, USA).

Case report

On admission

A 76-year-old woman who underwent surgical MVR with Magna Mitral Ease 25 mm (Edwards Lifesciences) 6 years previously presented with dyspnea with New York Heart Association (NYHA)-class III due to bioprosthetic mitral valve dysfunction.

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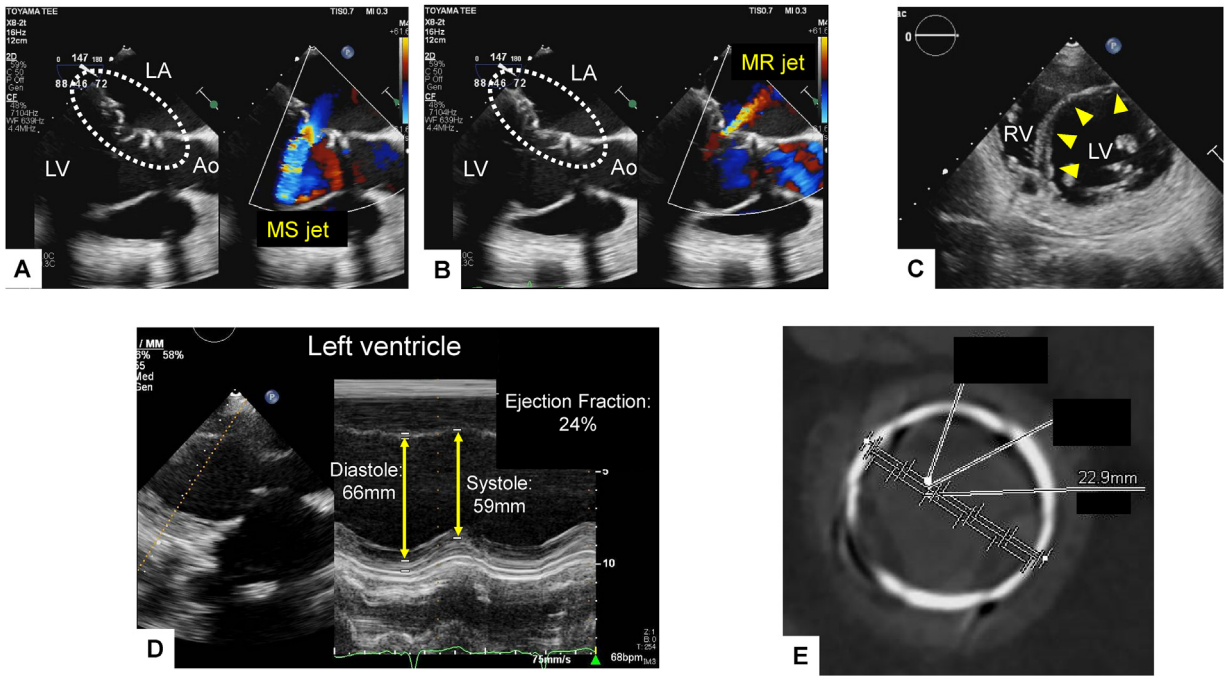

Fig. 1. Pre-procedural transesophageal echocardiography (TEE) and multi-detector computed tomography (MDCT).
(A) Left ventricular outflow tract view of TEE. The white-dot circle shows a failed Magna valve. Mosaic color means mitral stenosis (MS) jet. (B) Mosaic color means the mitral regurgitation (MR) jet. (C) Short-axis view of the LV. The yellow triangle shows thinned inter-ventricular septum. (D) Long-axis view of the LV. (E) The inner diameter of bioprosthesis measured using MDCT.
LA, left atrium; LV, left ventricle; Ao, aorta; RV, right ventricle.

Transesophageal echocardiography (TEE) showed severe stenosis (mean pressure gradient of 13 mmHg) and moderate regurgitation in the Magna (Fig. 1A and B).

Therapeutic strategy

The gold standard is a surgical re-MVR, but she had a low left ventricular ejection fraction of 24%, cardiac sarcoidosis (Fig. 1C and D), and long-term steroid use with 12.6% mortality risk by the Society of Thoracic Surgeons score. After a meticulous discussion over a high risk for surgical re-MVR, the heart valve team eventually chose TMVR-VIV.

The transapical approach has long been used in the USA and Europe for TMVR [3]. Its successful use has been reported also in Japan [4]. However, her impaired cardiac function with suspected residual myocardial inflammation by sarcoidosis urged us away from the transapical approach. Instead, we considered a transfemoral-transseptal approach using SAPIEN 3 as an off-label use. Written informed consent was obtained from the patient along with an approval from the local Institutional Review Board (MTIG2019002).

Preparation

The procedure was performed via transfemoral approach under general anesthesia using TEE and fluoroscopic images. A pacing wire was advanced via the right jugular vein to the right ventricle. Veno-atrial extracorporeal membrane oxygenation circuit was prophylactically set via left femoral vein and artery.

A 16-French eSheath (Edwards Lifesciences) was advanced via right femoral vein (Fig. 2A). After the puncture of the inter-atrial septum at postero-inferior location of the fossa ovalis with a SL-0 (Abbott, St Paul, MN, USA) and a NRG RF Transseptal Needle (Baylis Medical, Montreal, Canada), Agilis sheath (Abbott) was passed into the left atrium. A 0.035-in. 260-cm J-type-Radifocus wire (Terumo, Tokyo, Japan) was put into the left ventricle through the Magna and was exchanged to Safari-S wire (Boston Scientific, Natick, MA, USA).

Degenerated Magna and intra-atrial septum channel were both dilated with a Mustang 10 × 20 mm balloon (Boston Scientific) (Fig. 2B). Multi-detector computed tomography (MDCT) showed 23 mm of the internal diameter of bioprosthesis (Fig. 1E), which was confirmed by the valve-in-valve application (version 2.0, UBQO Limited, London, UK) [5], and we chose the SAPIEN 3 of 26 mm.

Valve replacement

The SAPIEN 3 was mounted upside down on a Commander Delivery System (Edwards Lifesciences) and advanced to the failed bioprosthesis. We confirmed the SAPIEN 3 position using fluoroscopy and deployed it using slow balloon inflation with nominal volume under the rapid pacing at 150 beats per minute (Fig. 2C and D). The post-dilation with +1 cc overfilling of the mount balloon was done given the residual mild peri-valvular leakage (PVL) (Video S1).

The shape of the deployed SAPIEN 3 was appropriate as a wider, cone-shaped, and ventricular end of the Magna (Fig. 2E). TEE showed no significant PVL and appropriate pressure gradient (Fig. 2F1–2, mean pressure: from 13 to 2 mmHg). Although we unavoidably created an iatrogenic atrial septal defect, partially right to left shunt on Doppler flow, we did not close the defect given the absence of desaturation. Hemostasis at the access site of Commander was achieved using a figure-of-eight suture [6].

Post-procedural course

The patient was extubated in the hybrid-operation room and transferred to the cardiac intensive care unit on the same day. The

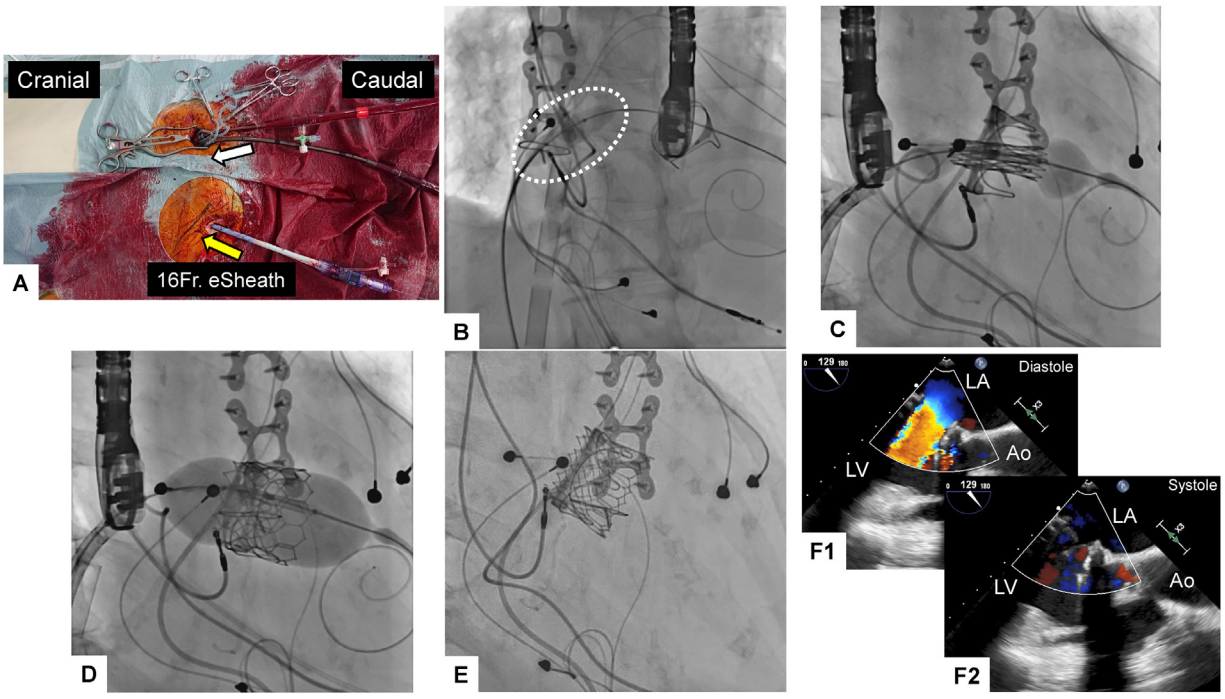

Fig. 2. Access site image, fluoroscopic images of transcatheter mitral valve-in-valve replacement and post-procedural transesophageal echocardiography. (A) Percutaneous access image. The eSheath inserted from the right femoral vein (yellow arrow). Veno-arterial extracorporeal membrane oxygenation circuit was set via the left-side vessels (white arrow). (B) Balloon atrial septostomy (white-dot circle). (C) Positioning of the SAPIEN 3 within the degenerated surgical valve over a Safari-S wire. And the ventricular end of the SAPIEN 3 was dilated over the tip of Magna. (D) The SAPIEN 3 was inflated. (E) The final fluoroscopic image of SAPIEN 3 in the degenerated valve. (F) No stenosis (F1) and no regurgitation (F2) at the SAPIEN3.
LA, left atrium; LV, left ventricle; Ao, aorta.

patient's symptoms immediately improved down to NYHA class I, and she was discharged on post-operative day 2. The right heart catheterization data were considerably improved including mean pulmonary artery wedge pressure from 30 mmHg to 11 mmHg (Fig. 3).

Discussion

Transseptal TMVR-VIV

Recently, bioprosthesis is preferred rather than the mechanical valves in surgical MVR given its favorable clinical outcomes. The rate of bioprosthetic mitral valve dysfunction requiring re-operation is approximately 20% during 10 years following MVR [1]. Despite appropriate clinical management, our patient had degenerated bioprosthesis at six years. The current guidelines recommend a surgical re-MVR for the first line therapy. However, given that Vohra et al. reported that the in-hospital mortality was 12% and survival rate at 5 years was 72% [7], we hesitated at such a surgical approach for her because of a high operative risk.

The use of TMVR-VIV is expanding in the USA and Europe [3]. Transapical approach is theoretically the shortest and coaxial route to deliver the SAPIEN 3 in the mitral position, whereas the transseptal approach is receiving great attention because of its lesser invasiveness and comparable outcomes [3]. After careful consideration of her comorbidities, we decided to perform transseptal TMVR-VIV for the first time in Japan.

Technical issues

Left ventricular outflow tract obstruction

This is a fatal peri-procedural complication. The risk factors are multifactorial, including septal thickness, elongated mitral valve leaflet, and depth of valve implantation [8]. Yoon et al. reported that estimated neo-left ventricular outflow tract (LVOT) area and mitral annulus-intraventricular septum distance measured by MDCT before procedure had discriminatory value for LVOT obstruction, with cut-off values of 1.7 cm^2 and 17.8 mm, respectively [9]. Her estimated neo-LVOT area was 4.9 cm^2 and mitral annulus-intraventricular septum distance was 19.1 cm, both of which did not reach proposed cut-offs, thanks to septal thinning due to cardiac sarcoidosis.

Migration of SAPIEN 3

Device-size selection and implant depth are important. MDCT and valve-in-valve application are useful tools to estimate appropriate device size as we did (Fig. 1E). The SAPIEN 3 should be completely expanded to achieve conical shape to prevent its migration into left atrium (Fig. 2E).

Peri-valvular leakage

PVL is associated with heart failure and hemolysis [10]. In our patient, mild leakage disappeared following a post-dilation with overfilling of the mount balloon.

Future perspective

This case demonstrates that the percutaneous transfemoral transseptal TMVR-VIV might be feasible for prohibitive surgical risk patients. Currently, TMVR-VIV using SAPIEN 3 has gotten CE Mark and US Food and Drug Administration approval for both aortic and mitral failed bioprosthesis. Japan approves the valve-in-valve procedure only for the aortic position. Durability and safety of TMVR-VIV using SAPIEN 3, particularly by comparing with surgical re-MVR, remain future concerns.

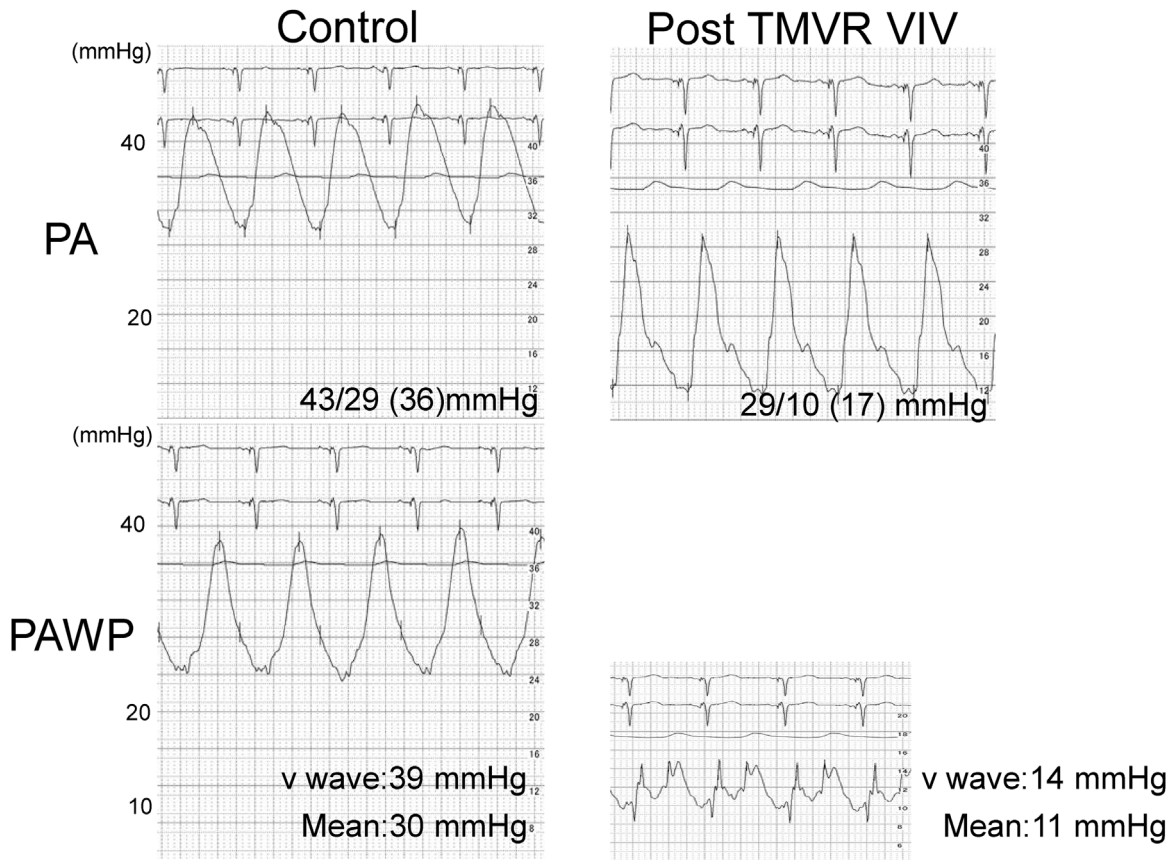

Fig. 3. The right heart catheterization data following TMVR-VIV.
PA, pulmonary artery pressure; PAWP, pulmonary artery wedge pressure; TMVR-VIV, transcatheter mitral valve-in-valve replacement.

Conclusions

To our knowledge, this is the first report of successful treatment by percutaneous transfemoral transseptal TMVR-VIV for degenerated mitral bioprosthesis. This therapeutic option might be considered as a valuable alternative to surgical treatment in prohibitive risk patients under careful evaluation by experienced heart valve team.

Conflict of interest

The authors declare no conflicts of interest.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.jccase.2020.09.003.

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