Case Report

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

Hiroshi Ueno (MD, PhD)*, Yuki Hida (MD), Yohei Ueno (MD), Shuhei Tanaka (MD, PhD), Ryuichi Ushijima (MD, PhD), Mitsuo Sobajima (MD, PhD), Nobuyuki Fukuda (MD, PhD), Teruhiko Imamura (MD, PhD, FJCC), Akiyo Kameyama (MD), Ryosuke Komiya (MD), Hisakatsu Ito (MD, PhD), Shigeki Yokoyama (MD), Toshio Doi (MD, PhD), Kazuaki Fukahara (MD, PhD), Koichiro Kinugawa (MD, PhD, FJCC)

Cardiovascular Center, Toyama University Hospital, Toyama, Japan

ARTICLE INFO

Article history:
Received 22 May 2020
Received in revised form 23 July 2020
Accepted 7 September 2020

Keywords:
Valve-in-valve
Transcatheter mitral valve replacement
Percutaneous transapical approach
Transfemoral approach

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.

© 2020 Japanese College of Cardiology. Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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.

* Corresponding author at: Cardiovascular Center, Toyama University Hospital, Sugitani 2630, Toyama-city, Toyama, Japan. E-mail address: hueno@med.u-toyama.ac.jp (H. Ueno).
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 (MITI2019002).

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 posteroinferior 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
multifactorial, transseptal degenerated 12\% and transseptal (Fig. 3).

Discussion

Transseptal TMVR-VIV

Recently, bioprostheses are 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 bioprostheses 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.
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.

Acknowledgments

The authors express special gratitude to Prof. Mamoo Nakamura of Cedars-Sinai Medical Center, and Dr Norio Tada of Sendai Kousei Hospital, for their technical expertise and assistance.

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.

References

[1] Bourguignon T, Lorraine A, Stablo B, Loardi C, Mirza A, Candolfi P, et al. Very late outcomes for mitral valve replacement with the Carpentier-Edwards pericardial bioprosthesis: 25-year follow-up of 450 implantations. J Thorac Cardiovasc Surg 2014;148:2004–11.
[2] Kamioka N, Babalarios V, Morse MA, Frissoli T, Lerakis S, Iturbe JM, et al. Comparison of clinical and echocardiographic outcomes after surgical redo mitral valve replacement and transcatheter mitral valve-in-valve therapy. J Am Coll Cardiol Interv 2018;11:1131–8.
[3] Guerrero M, Vemulapalli S, Xiang Q, Wang DD, Eleid M, Cabalka AK, et al. Thirty-day outcomes of transcatheter mitral valve replacement for degenerated mitral bioprostheses, failed surgical ring, and native valve with severe mitral annulus calcification in the United States. Circ Cardiovasc Interv 2020;13:e008425.
[4] Tada N, Enya T, Sakurai M, Ootomo T, Hata M. Transcatheter valve-in-valve implantation for failed mitral prosthesis: the first experience in Japan. Cardiovasc Interv Ther 2017;32:82–6.
[5] Bapat V. Valve-in-valve apps: why and how they were developed and how to use them. EuroIntervention 2014;10(Suppl. U):U44–51.
[6] Aytemir K, Canpolat U, Yorgun H, Evranos B, Kaya EB, Sahiner ML, et al. Usefulness of ‘figure-of-eight’ suture to achieve haemostasis after removal of 15-French calibre femoral venous sheath in patients undergoing cryoablation. Europace 2016;18:1545–50.
[7] Vohra HA, Whistance RN, Roubelakis A, Burton A, Barlow CW, Tsang GMK, et al. Outcome after redo-mitral valve replacement in adult patients: a 10-year single-centre experience. Interact Cardiovasc Thorac Surg 2012;14:575–9.
[8] Divr D, Webb J. Mitral valve-in-valve and valve-in-ring: technical aspects and procedural outcomes. EuroIntervention 2016;12:Y93–6.
[9] Yoon SH, Bleiziffer S, Latib A, Eschenbach L, Ancona M, Vincent F, et al. Predictors of left ventricular outflow tract obstruction after transcatheter mitral valve replacement. J Am Coll Cardiol Interv 2019;12:182–93.
[10] Asami M, Pilgrim T, Windecker S, Fabien Praz F. Case report of simultaneous transcatheter mitral valve-in-valve implantation and percutaneous closure of two paravalvular leaks. Eur Heart J Case Rep 2019;3:1–6.