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A novel case of transcatheter mitral valve-in-valve replacement using Mi-thos™ system

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Transcatheter mitral valve replacement (TMVR) has become an alternative to surgical mitral valve replacement for the treatment of patients with severe mitral insufficiency (MI) who are at very high or prohibitive surgical risk.[1] Because of impaired left ventricular dysfunction and previous cardiac surgery, some aged patients with degenerated bioprosthetic mitral valve and mitral regurgitation were refused to redo surgery.[2] Increasing demand are required for minimally invasive treatment of these patients. Hundreds of patients worldwide have been treated with a transcatheter mitral valve-in-ring or valve-in-valve procedure using transcatheter aortic valve.[3] However, rare case of transcatheter mitral valve-in-valve/ring replacement using transcatheter mitral valve system was reported. Here, we reported a successfully case of transcatheter mitral "valve-in-valve" replacement for the treatment of bioprosthetic mitral valve degeneration and severe regurgitation with domestic Mi-thos™ valve.

An 85-year-old man diagnosed with degenerated bioprosthetic mitral valve and severe regurgitation was referred to our hospital. The medical history of this patient included bioprosthetic valve replacement with a 29 mm Hancock-II (Medtronic, MN, USA) mitral valve for nine years, permanent cardiac pacemaker implantation for four years after the surgery for the reason of new-onset atrial fibrillation with second degree atrioventricular block. Transthoracic echocardiogram (TTE) revealed bioprosthetic mitral valve degeneration and severe transvalvular regurgitation, maximum and mean transvalvular gradients were 21 mmHg and 17 mmHg, with a compromised left ventricular ejection fraction (45%) (Figures 1A & 1B). The informed consent was obtained after having discussed all available treatment methods. Since the patient was highly symptomatic and very high risk of thoracotomy surgery (Logistic EuroSCORE II = 19.36%), transcatheter mitral valve replacement was scheduled.

The ideal transcatheter mitral valve size for the valve-in-valve procedure was selected based on the preoperative evaluation of cardiac computed tomography angiography (CTA) and 3D printing simulation (Figures 1C & 1D). A 29 mm Mi-thos™ valve (NewMed Medical Co., Ltd., Shanghai, China) was chosen and 3D printing *in vitro* simulation confirmed the low risk of left ventricular outflow tract obstruction (LVOTO) and paravalvular leakage (PVL) (Figures 1E & 1F). The operation was performed with fully anesthetized and mechanically ventilation. Transesophageal echocardiogram (TEE) was used for intraoperative evaluation. Both right femoral artery and vein were punctured and cannulated with 6F sheaths. Then, a temporary pacemaker electrode was inserted to the right ventricle through the vein sheath. Meanwhile, a 6F pigtail catheter was advanced through the right femoral artery to the left ventricle. The standard apical access was obtained and a hexagonal suture were placed around the apical entry site. A cranial right-anterior-oblique angulation was adjusted to provide good visualization of both left ventricle and atrium. Ventriculograms were taken to show the transvalvular regurgitation of bioprosthetic mitral valve, and the shape of the left ventricle. At the same time, Mi-thos™ valve of 29 mm size was selected and assembled *in vitro* in a sterilized iced saline environment. After apical puncture, a 6 Fr sheath was inserted. A 6F pigtail catheter together with a J-tipped 0.035-inch guide wire was inserted and advanced across the bioprosthetic mitral valve into the left atrium. Then, a 260 cm Lunderquist super stiff wire (Cook Medical In., Bloomington, IN, USA) was exchanged. The Mi-thos™ valve, loaded in its delivery system, was inserted over the Lunderquist guide wire and advanced retrogradely across the mitral valve into the left atrium. By retrieving the outer sheath of the delivery

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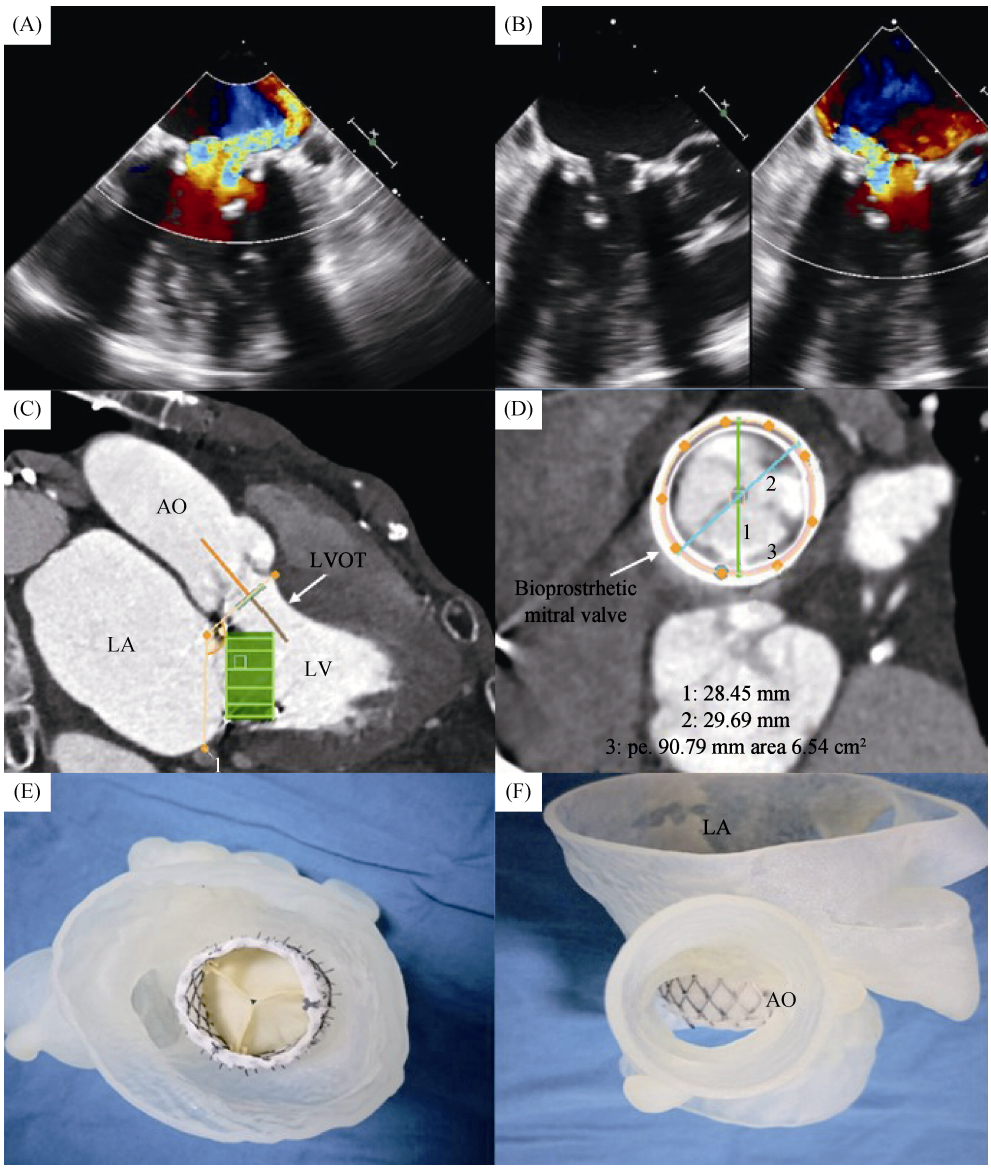

Figure 1. Preoperative imaging data of patients. (A & B): Transesophageal echocardiography images; (C & D): preoperative evaluation of cardiac computed tomography angiography remodeling; and (E & F): preoperative evaluation of 3D printing simulation. AO: aortic; LA: left atrium; LV: left ventricular; LVOT: left ventricular outflow tract.

system, the atrial skirt, designed to fit the D-shaped mitral annulus, was released while the ventricular portion of the device was still partially confined to the sheath. Radiopaque markers were visualized on the metal frame of the Mi-thos^{TM} valve to achieve accurate alignment and engagement of the flat atrial aspect of the Mi-thos^{TM} valve with the mitral ring using echocardiographic and fluoroscopic guidance. After verifying the position and direction of the Mi-thos^{TM} valve, the whole system was retracted and seated on the mitral ring. Then, under rapid pacing of 140 per minutes, the ventricular portion of the Mi-thos^{TM} prosthesis was deployed and released from the delivery system, just anchored at the bioprosthetic mitral ring (Figures 2A–D). Valve position and function were evaluated by TEE (Figures 2E & 2F). Postoperative ventriculograms confirmed both the position and the shape of the Mi-thos^{TM} valve was perfect, and revealed no transvalvular insufficiency, no PVL, or no LVOTO obstruction. Then the delivery system was removed through the apex incision, and hemostasis was achieved using the previously placed apical strings.

After incision closure, the patient was evacuated from the ventilator and transported to cardiac intensive care unit. The postoperative recovery was uneventful and the patient was discharged four days after operation in good clinical condi-

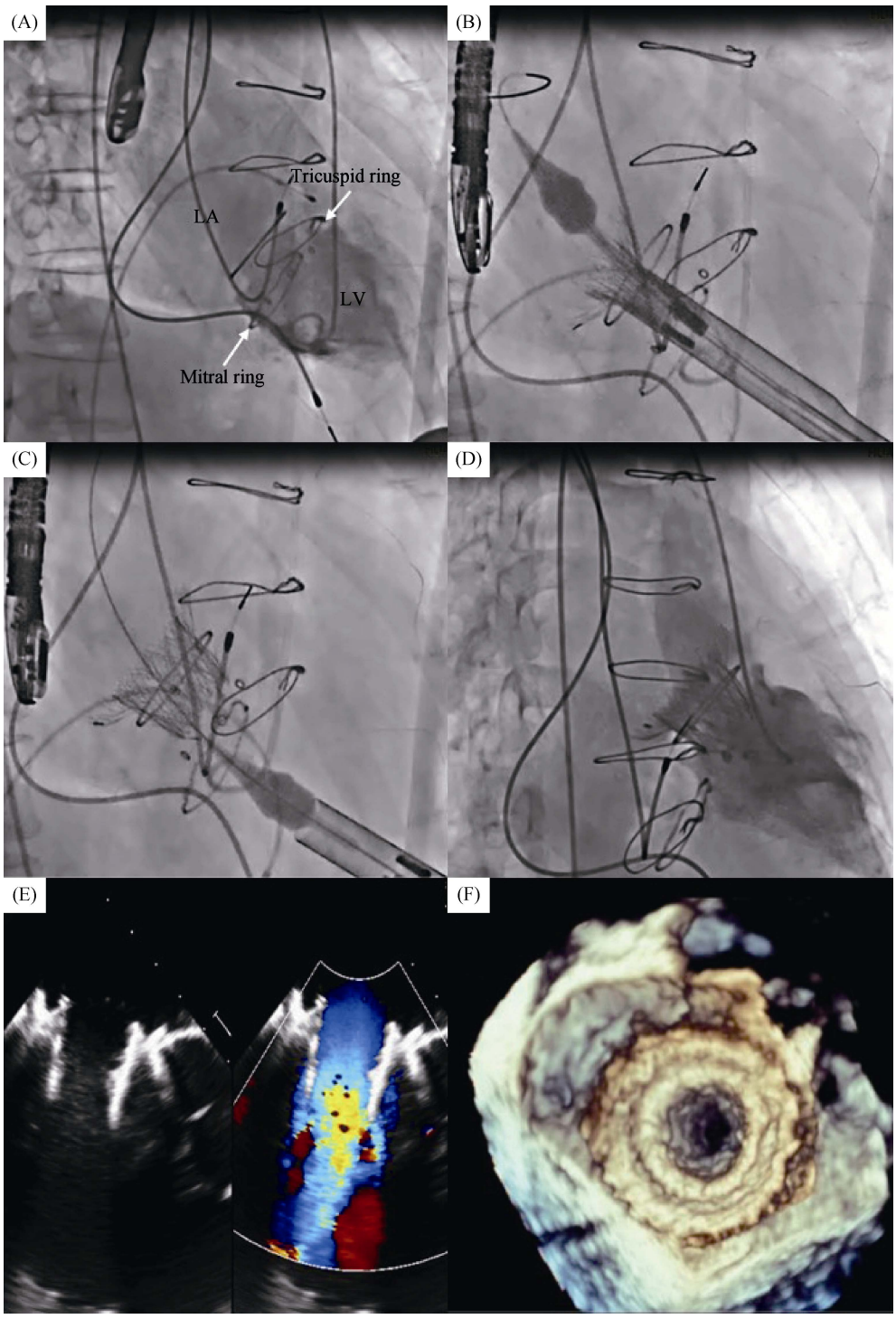

Figure 2. Intraoperative digital subtraction angiography images and postoperative transesophageal echocardiography images. (A): Preoperative left ventriculography; (B): transcatheter apical implantation of interventional valve; (C): release of interventional valve; (D): postoperative left ventriculography; and (E & F): postoperative transesophageal echocardiography images. LA: left atrium; LV: left ventricular.

tion. At discharge, TTE revealed excellent valve position and function without any significant transvalvular or paravalvular regurgitation, as well as no LVOTO, with maximum and mean gradients were 10 mmHg and 6 mmHg.

Though valve replacement in thoracotomy surgery remains the golden standard for various mitral valve diseases,

cardiopulmonary bypass, cardiac arrest, and the associated high rates of mortality and morbidity makes it extremely risky for elderly and high-risk patients with MI, especially for valvular degeneration patient who need to do secondary thoracotomy.[4,5] Transcatheter mitral valve replacement has been performed for patients with degenerated bioprosthetic mitral valve or ring, and showed excellent clinical results.[6,7]

In the past five years, TMVR devices have emerged in an endless stream all over the world, and the success of clinical trials has been frequently reported.[8] But up to now, the popularization of this technique is still very limited, which is not only related to the particularity of mitral valve structure, but also related to the difficulty of preoperative screening and evaluation.[9] Considering that the mitral valve is a spatial three-dimensional structure, the lesion modes are diverse and dynamic in the cardiac cycle, TEE and computed tomography analysis have great limitations.[10] Therefore, through 3D modeling of patients' CTA data and further 3D printing, we can stereoscopically display the characteristics of mitral-related structures.[11] By further *in vitro* surgical simulation, the operation-related risks, such as LVOTO, PVL, and cardiac fracture, were assessed more accurately.[12,13]

The Mi-thos™ valve (NewMed Medical Co., Ltd., Shanghai, China), we used in this case is a self-expanding bioprosthesis with cross-linked bovine pericardial tissue leaflets mounted inside a nitinol self-expanding frame. The valve is loaded into a 28Fr–32Fr caliber trans-apical delivery system, which was leading by a self-dilating tip to facilitate transition through the apex and the mitral valve complex and to reduce system friction. The atrial portion of the device has a D-shaped design to fit the saddle-shaped mitral annulus. The ventricular portion of the device comprises a covered skirt to prevent PVL and secure barbs to prevent retrograde migration during systole. On the end of the ventricular side, three anchoring points permit retrieval of the device into the delivery system. In particular, the Mi-thos™ valve is retrievable and repositionable during all stages of the procedure until the final step of ventricular deployment. For valve-in-valve procedure, artificial valves or ring can provide radial support, and the TMVR can be accomplished safe and sound with current interventional aortic valves. However, there are limited types and sizes of transcatheter aortic valve available in China at present, which makes potential problems for off-label using. Therefore, special transcatheter mitral valve is the best choice for this patient. This Mi-thos™ valve is larger and suitable for mitral valve dissection, skirt structure is helpful to prevent valve displacement and PVL, and shorter stents can effectively prevent LVOTO.

This case demonstrated for the first time the feasibility of transapical Mi-thos™ valve in degenerated mitral bioprotheses in China. The easy controlled system with remarkably stable hemodynamics throughout the procedure offers a new and less invasive alternative in selected cases. However, long-term clinical trials are required to confirm the efficacy and safety.

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