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CASE REPORT

CLINICAL CASE

Transcatheter Mitral Valve Repair Using a Novel Device for a High-Surgical-Risk Patient With DMR

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ABSTRACT

Transcatheter edge-to-edge repair (TEER) has been established as a safe and effective option for treating patients with severe symptomatic degenerative mitral regurgitation (MR) who are at prohibitive surgical risk. However, the significant cost presents a considerable disease burden in low-income countries. This case details the treatment of a high-surgical-risk patient with severe degenerative MR by using the GeminiOne (Peijia Medical) system—a novel Chinese TEER device. (J Am Coll Cardiol Case Rep 2024;29:102334) © 2024 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

HISTORY OF PRESENTATION

A 74-year-old man was admitted to our hospital with recurrent chest tightness and dyspnea refractory to medical therapy (NYHA functional class IV). His past history included chronic congestive heart failure, coronary artery disease, hypertension, vertebral artery stenosis, chronic obstructive pulmonary disease, and renal insufficiency. During the physical examination, a III/VI blowing holosystolic murmur was detected at the apex, along with rales in both lungs.

LEARNING OBJECTIVES

- To understand the design and mechanism of the novel-designed TEER device.
- To recognize that staged TEER is a feasible therapy for patients with multiple left-sided VHD.

PAST MEDICAL HISTORY

He received a diagnosis of severe pure aortic regurgitation (AR) and mild to moderate functional mitral regurgitation (MR) with a compromised left ventricular ejection fraction (LVEF) of 38%, and he had undergone transapical transcatheter aortic valve replacement (TA-TAVR) using a novel-designed J-Valve transcatheter aortic valve replacement (TAVR) system (JC Medical) 3 years earlier. Notably, his heart failure symptoms were partially relieved after the procedure, and his left ventricular diameter returned to a normal size; his LVEF improved during follow-up. However, he recently developed paroxysmal nocturnal dyspnea, accompanied by recurrent chest tightness and cough.

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ABBREVIATIONS AND ACRONYMS

AR = aortic regurgitation

DMR = degenerative mitral regurgitation

LVEF = left ventricular ejection fraction

MR = mitral regurgitation

TAVR = transcatheter aortic valve replacement

TA-TAVR = transapical transcatheter aortic valve replacement

TEE = transesophageal echocardiography

TEER = transcatheter edge-to-edge repair

VHD = valvular heart disease

DIFFERENTIAL DIAGNOSIS

The differential diagnosis for patients with recurrent chest tightness and dyspnea includes coronary artery disease, dilated cardiomyopathy, restrictive cardiomyopathy, valvular heart disease, and respiratory disease. In this case, the physical examination revealed a III/VI blowing holosystolic murmur at the apex, strongly suggesting the possibility of MR.

INVESTIGATIONS

On presentation, echocardiography revealed anterior leaflet prolapse in the A1 and A2 regions with chordal rupture, resulting in severe eccentric degenerative MR (DMR) (vena contracta width, 8.64 mm; prolapse height, 5 mm, and width, 9 mm), with a preserved LVEF and normal function of the TA-TAVR valve (**Figures 1A to 1C**). The echocardiographic data before transcatheter edge-to-edge repair (TEER) are listed in **Table 1**. Given the patient's advanced age and significant comorbidities, posing a high surgical risk (The Society of Thoracic Surgeons score >8%), the multidisciplinary heart team decided that TEER would be suitable for this patient. The local ethics committee approved this study.

The device used in this case is a novel-designed TEER system—GeminiOne (Peijia Medical), which incorporates features from the 4-generation TEER system, including independent leaflet grasping and multiple clamp sizes (4 different arm sizes, 4 mm and 6 mm in clip arm width and 10mm and 13 mm in clip arm length). Its unique feature lies in its innovative sliding groove mechanism, coupled with a threaded structure, that allows for automatic locking and release of the clip at any angle. This capability permits adjustment of clipping force and balancing of leaflet tension during the procedure (**Figures 2A to 2D and 3**).

MANAGEMENT

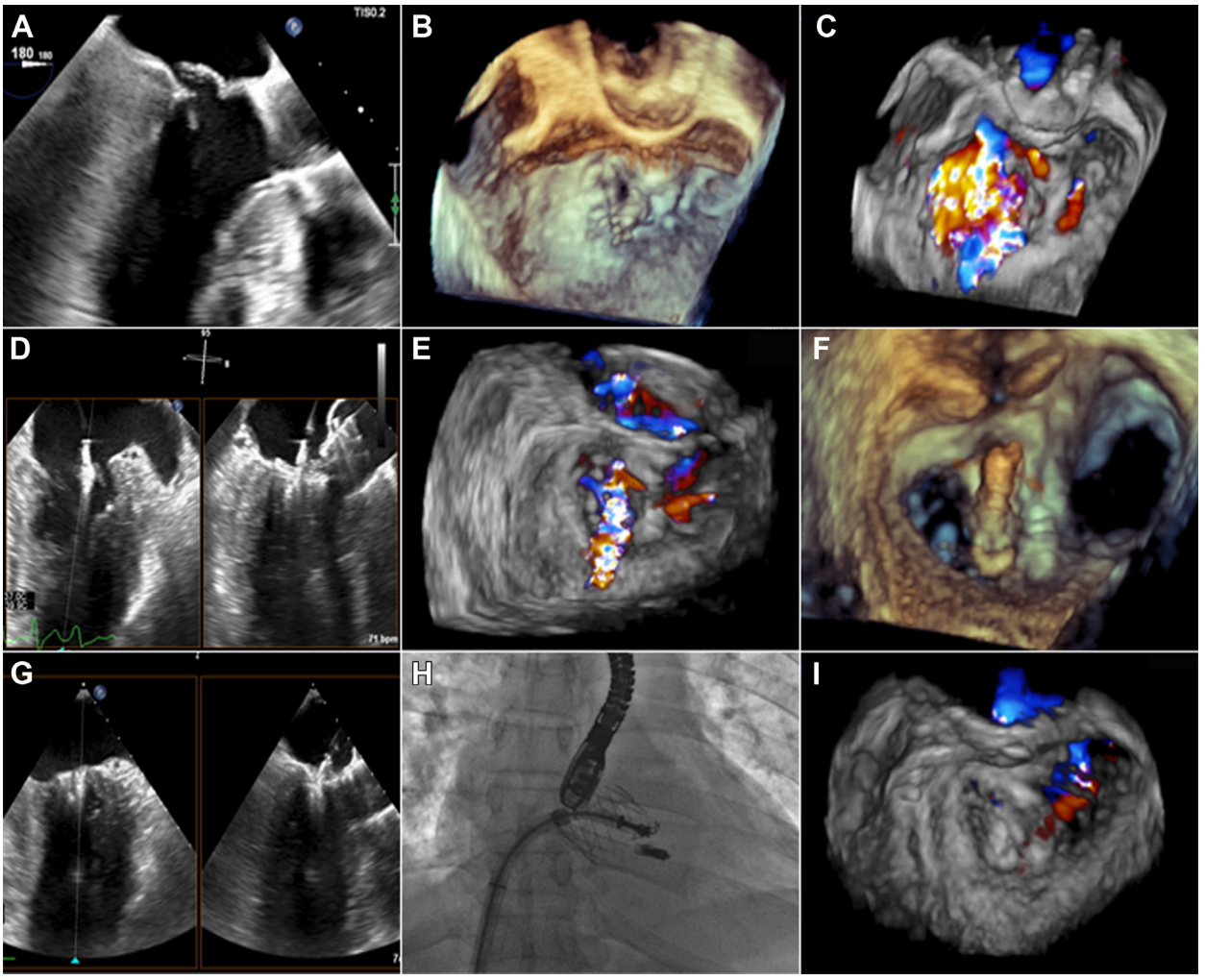
The procedure was conducted while the patient was under general anesthesia. Guided by transesophageal echocardiography and fluoroscopy, a super-stiff guidewire was advanced through the puncture site following interatrial septum puncture and positioned into the left upper pulmonary vein. Subsequently, a 22-F guiding sheath was introduced into the left atrium along the guidewire. The TEER system was then delivered to the left atrium and targeted to the prolapsed section of the mitral valve by adjusting the curving angle until perpendicular to the mitral annulus. The clip arms were opened and rotated until perpendicular to the line of coaptation. The device was implanted by independently grasping to maximize capture of the affected leaflet segments. Initially, a first clip of 0626 size (6-mm width with 13-mm arm length) was placed in the A2/P2 region, and postimplantation transesophageal echocardiography (TEE) revealed a significant lateral residual regurgitant jet. Subsequently, a second clip of 0620 size (6-mm width with 10-mm arm length) was placed adjacent to the first clip (**Figures 1D to 1I**) (Video 1). MR was significantly reduced from severe (4+) to none (0+), with a mean transvalvular gradient of 4 mm Hg. Immediate postprocedure TEE confirmed the correct position of the clips (Video 2). Postoperatively, the patient's symptoms improved without any intervention-related complications, and he was discharged 6 days after the intervention. Transthoracic echocardiography before discharge confirmed the stability of the devices and the sustained reduction in MR grade.

DISCUSSION

MR is the most frequent valvular heart disease (VHD) in Europe.[1] It is similarly considered the most common VHD in China, affecting nearly 1.1% of the general adult population and correlating with an increased risk of cardiac death.[2,3] It has been established that TEER is a safe and effective treatment option for patients not eligible for a surgical approach. However, the devices approved by the U.S. Food and Drug Administration, such as MitraClip (Abbott Vascular) and PASCAL (Edwards Lifesciences), come at a cost ranging between $33,000 and $120,000 (U.S. dollars) in Western countries.[4] This substantial pricing constitutes a significant disease burden in low-income countries, where TEER devices are typically not subsidized by health insurance. Hence, the high cost of the device has hindered the widespread application of TEER in China, thus leading to a much lower frequency of TEER procedures in Chinese patients with MR.[2] The novel TEER system offers a cost-effective alternative treatment option for patients with MR.

This device is a novel TEER system. Unlike current available devices such as the MitraClip and the PASCAL system, this system has been designed with an innovative sliding groove mechanism, together with a threaded structure, enabling automatic locking and release of the clip at any angle. This feature allows the operator to adjust the clipping force and balance the leaflet tension during the procedure. Additionally, given the unique locking mechanism (at

FIGURE 1 Procedural Steps of Mitral Valve Repair With the Novel System



(A to C) 2- and 3-dimensional transesophageal echocardiography showing anterior leaflet prolapse(A1-A2) with severe mitral regurgitation. (D) Transesophageal echocardiography X-plane showing leaflet capture with the first device. (E) Three-dimensional transesophageal echocardiography view with color Doppler imaging showing a residual regurgitant jet on the lateral side after first clip implantation. (F to H) The second device was implanted lateral and adjacent to the first device. (I) Three-dimensional transesophageal echocardiography imaging confirming no residual mitral regurgitation after implantation of 2 clips.

the tip of the clip), the height of the clip has been shorted in its closed state compared with MitraClip, thereby requiring less supravalvular height for delivery and positioning. Moreover, the maximum total clip capture length (0626 size) reaches 25 mm at 120° and 26 mm at 180°, superior to the MitraClip G4 system with the XTW clip (Figures 2A to 2D). This system also enables independent leaflet grasping with 4 different clamp sizes (4 mm and 6 mm in arm width and 13mm and 10mm in arm length), thus providing the flexibility to treat complex anatomy.

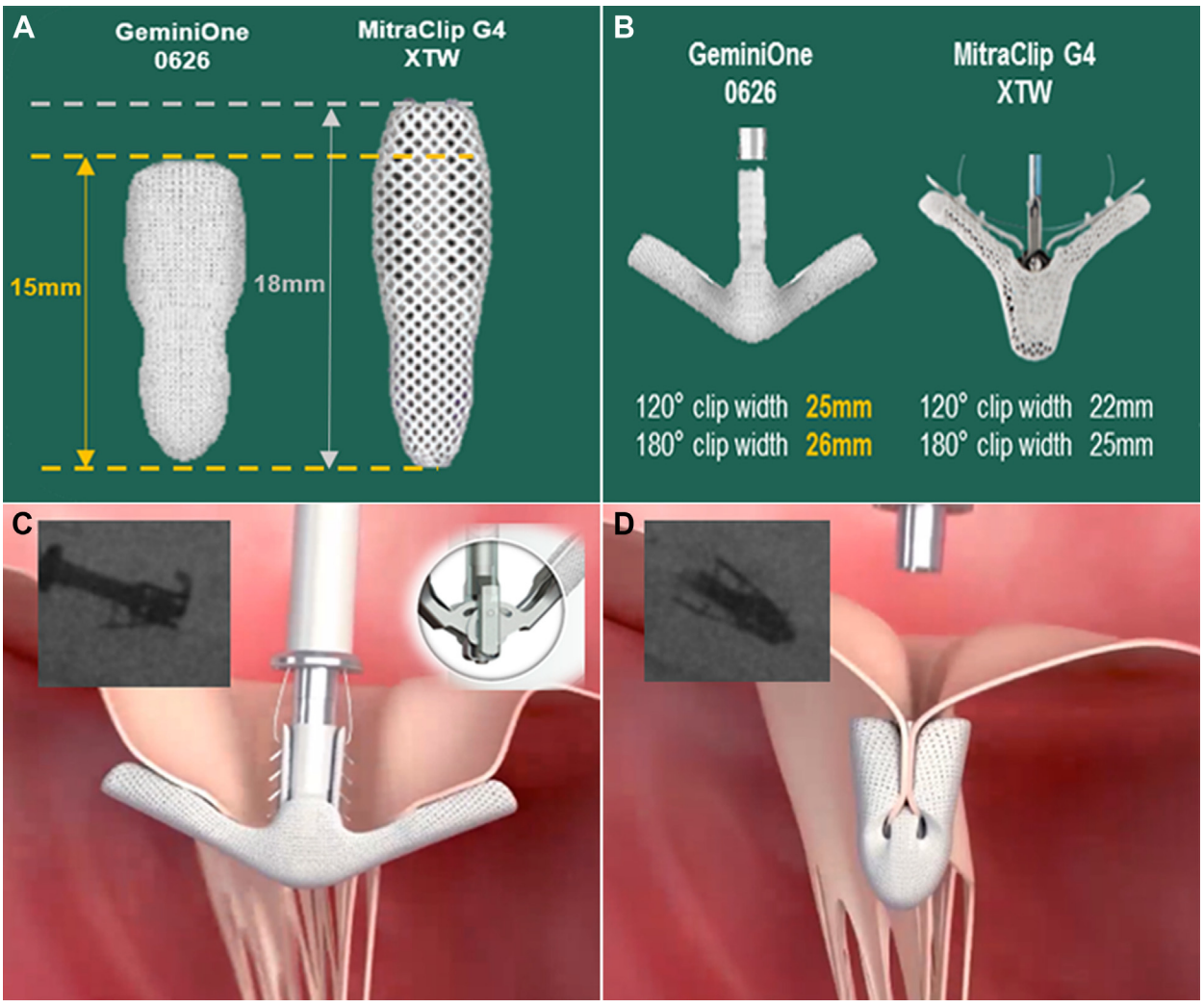
Multiple left-sided VHD is highly prevalent. Previous studies have observed that the combination of MR and AR is relatively common, and the presence of MR is independently associated with all-cause

TABLE 1 Echocardiographic Parameters Before Transcatheter Edge-to-Edge Repair

Left ventricular end-diastolic volume, mL	103
Left ventricular end-systolic volume, mL	41
Left ventricular ejection fraction, %	59
Left atrial volume, mL	60.5
Right ventricular systolic pressure, mm Hg	20
Right ventricular fractional area change, %	42.7
Mitral valve orifice area, cm^2	4.4
Carpentier classification type	II
MR grade	4+
Vena contracta width, mm	8.64
Prolapse height, mm	5
Prolapse width (A1-A2 region), mm	9

A1 and A2 = anterior mitral valve leaflets; MR = mitral regurgitation.

FIGURE 2 **Features of the Novel Transcatheter Edge-to-Edge Repair System**



(A and B) Features of this system (O626 size) in comparison with MitraClip (XTW) (Abbott Vascular). (C and D) Schematics of leaflet capture and locking and release of the clip.

mortality.[5,6] Most patients with functional moderate to severe MR would benefit from both percutaneous and surgical aortic valve implantation, showing a significant improvement in MR. However, a minority of these patients experienced worsening of MR. Different from most cases, the degree of MR in our patient progressed to 4+ after TA-TAVR, secondary to severe anterior leaflet prolapse. In retracing the past course, we found that this patient had been regularly followed up after TA-TAVR until 2 years earlier, with a normally functioning mitral valve demonstrated by transthoracic echocardiography at the last follow-up. In the absence of more records between the 2 years, it is difficult to figure out the exact cause for the progression of MR. We could rule out the possibility that the mitral apparatus was impaired during the TA-TAVR procedure. Regardless of the ambiguous origin, this case highlights that the TEER procedure following TA-TAVR remains effective in reducing residual MR, consistent with a previous study conducted by Witberg et al.[7] For patients with MR that does not improve sufficiently following TAVR, a

FIGURE 3 Photographs of the Novel Transcatheter Edge-to-Edge Repair System

staged intervention such as TEER is still associated with an improvement in MR grade and favorable heart function.[7]

FOLLOW-UP. At 6-month follow-up, the patient had no particular symptoms, with New York Heart Association functional class II. The transthoracic echocardiogram revealed trivial MR (0+), and both the aortic prosthesis and the mitral valve were functioning normally.

CONCLUSIONS

This case exemplifies the safety and efficacy of using the novel China-made transcatheter repair device to address severe DMR following TA-TAVR.

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KEY WORDS China medical devices, mitral regurgitation, transcatheter mitral valve edge-to-edge repair

APPENDIX For supplemental videos, please see the online version of this paper.