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CASE REPORT

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Transcatheter mitral valve repair in a high-surgical risk patient with severe degenerative mitral regurgitation using the novel DragonFly™ Transcatheter Repair device—First in man implantation in China

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Abstract

Transcatheter repair of mitral regurgitation (MR) by edge-to-edge therapy has become increasingly accepted for patients with severe MR at high or prohibitive surgical risk in primary or degenerative mitral regurgitation (DMR). The technological approach has evolved from the initial transcatheter edge-to-edge device to improve on its acute reduction in MR and durability of results, particularly in complex primary pathology. In this study, we reported the first case of DragonFly™ Transcatheter Valve Repair device in a patient with severe DMR.

KEYWORDS

mitral valve disease, percutaneous intervention, percutaneous valve therapy, structural heart disease intervention

1 | INTRODUCTION

Mitral regurgitation (MR) is the most common valvular heart disease, and more than 10% of the population above 75 years of age have moderate to severe MR, resulting from degenerative (primary), functional (secondary), or mixed etiologies.[1] Although mitral valve surgery is the standard treatment for degenerative mitral regurgitation (DMR), only about 40% of such patients received surgery in the European Heart Survey.[2] For those with DMR and advanced age, comorbidities, or functional mitral regurgitation (FMR), mitral valve surgery is not commonly performed due to prohibitive surgical risk, or in the case of FMR, lack of supporting data. Transcatheter edge-to-edge mitral repair technologies now have regulatory approval and guideline recommendations as a treatment option for patients severe symptomatic DMR at prohibitive surgical risk or for those with FMR failing guideline directed medical therapy. Two current edge-to-edge repair systems have regulatory approval, including the MitraClip (Abbott Vascular, Santa Clara, CA) and PASCAL Transcatheter Repair System (Edwards Lifesciences, Irvine, CA). The Mitraclip has been extensively studied and shows excellent safety and very good efficacy results.[3-5] The PASCAL device has encouraging early clinical trial data and is currently in randomized Pivotal trials.[6] In this study, we report the first-in-man implantation of the DragonFly™ Transcatheter Valve Repair device—a novel transcatheter mitral edge-to-edge repair device in treatment of a prohibitive-risk patient with severe DMR (Figure 1).

2 | CASE REPORT

An 83-year-old frail male (body weight 45 kg) with controlled hypertension, and chronic lung disease, presented with New York Heart Association (NYHA) class III–IV heart failure symptoms and pulmonary edema refractory to medical treatment. Transthoracic echocardiogram

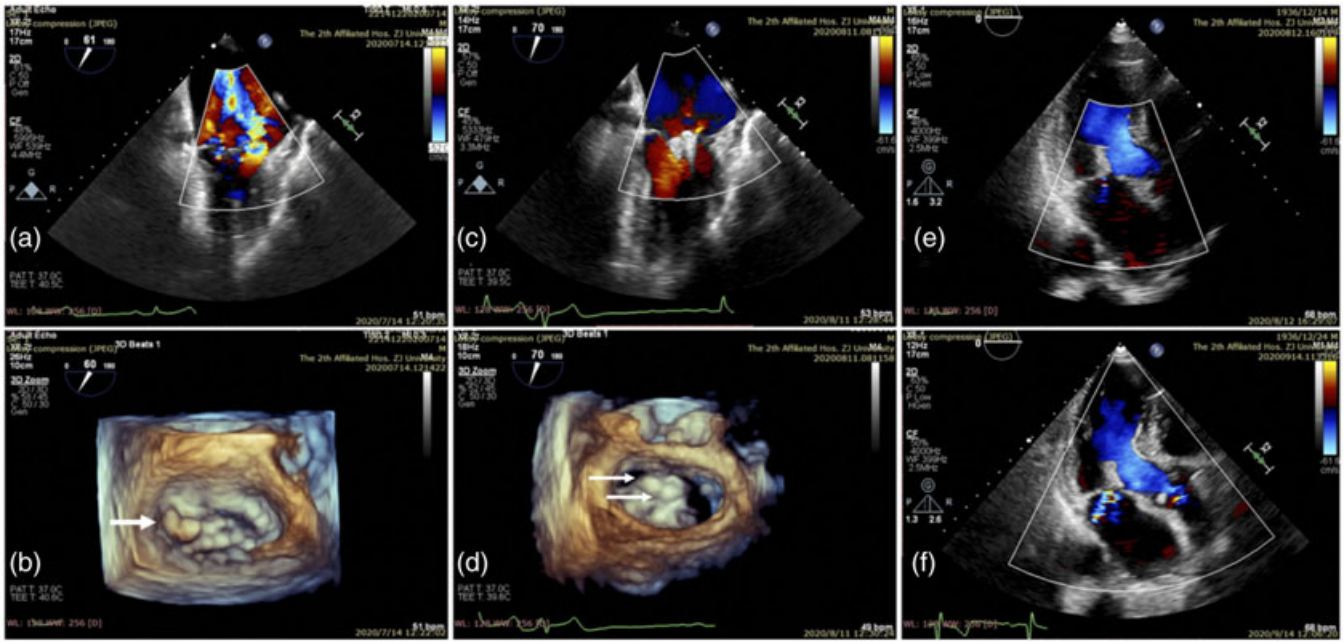

FIGURE 1 Echocardiogram imaging of this patient. (a) Color Doppler of the mitral valve on transesophageal echocardiography (TEE) prior to implantation. (b) Posterior leaflet prolapse involving the P1 segment (arrow) prior to implantation. (c) Color Doppler of the mitral valve after procedure. (d) 3D TEE view of the mitral valve from the left atrial perspective after procedure; the clips of DragonFly™ located at the prolapsing P1 segment (arrows). (a) Transthoracic echocardiogram at discharge. (f) Transthoracic echocardiogram at 1-month follow-up

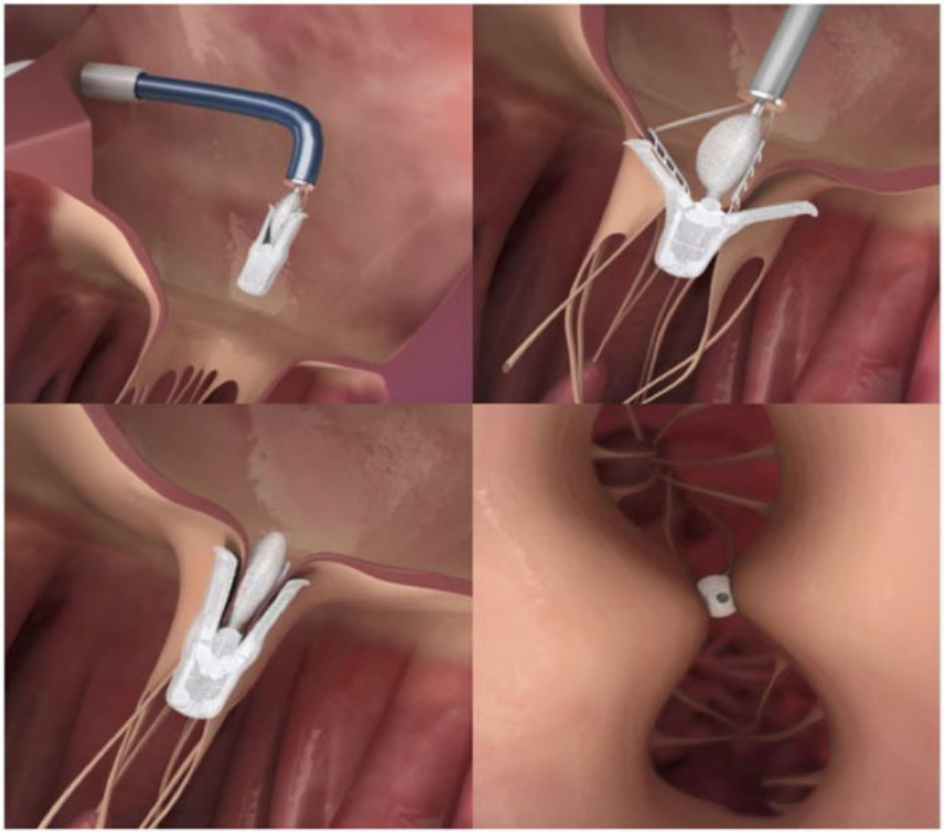

FIGURE 2 Feature of DragonFly™ system

(TTE) revealed severe MR with normal left ventricular systolic function. A transesophageal echocardiogram (TEE) was performed to further determine the mechanism of the MR, and revealed a prolapsing lateral P2 segment with flail P1 segment of the mitral valve with 8 mm flail width (Figure 1a,b). The vena contracta width was 7 mm, resulting in an eccentric jet into the left atrium, with a calculated

effective regurgitant orifice area (EROA) of 0.43 cm^2, consistent with severe MR. The anterior and posterior leaflet measured 23 mm/11 mm at A2/P2 region and the mitral valve area (MVA) was 4.4 cm2, with a mean inflow gradient of 1 mmHg and very dilated left atrium. Considering the prohibitive surgical risk and frailty of this patient, transcatheter mitral repair using the DragonFly™ system was chosen after a multidisciplinary heart team discussion.

The DragonFly™ system used in this patient is a novel transcatheter mitral edge-to-edge repair device that is delivered by a coaxial delivery system capable of three-dimensional articulation, and has an implanted edge-to-edge coaptation device (Figure 2). The key features of this device include a central nitinol spacer between the leaflet grasping arms to provide better leaflet coaptation without tensioning the leaflets, along with the ability to independently grasp each leaflet (Figure 1). The entire delivery system, including the guiding sheath and device delivery catheter has calibration markers to facilitate the reliable positioning of the device (Figure 3). The DragonFly™ valve repair device comes in four different sizes (Supplementary Figure 1), all with independent leaflet grasping, which facilitates tailoring the therapy to the valve complexity.

The procedure was conducted under general anesthesia with endotracheal intubation and transesophageal echocardiographic (TEE) and fluoroscopic guidance in a hybrid operative room. After right femoral venous access was obtained, under TEE guidance, targeted trans-septal puncture across the interatrial septum was performed and the guiding sheath positioned in the left atrium. The DragonFly™ Mitral Repair device was then delivered to the left atrium, and under TEE guidance, the delivery system was articulated to position the device over the P1 prolapse section. The device arms were opened, rotated until perpendicular to the line of coaptation, and advanced into the left ventricle. The anterior and posterior mitral valve leaflets were then serially grasped and the device was closed until the leaflets were in apposition with the central spacer. Due to the significant width of the prolapse, two DragonFly™ devices, both of the wide and short arm length variants were used to treat the prolapsing segment. After the second DragonFly™ device was deployed, the prolapse of P1 region was completely eliminated with significant MR reduction from 4+ to 1+ (Figure 1c,d) and mean inflow gradient was measured at 2 mmHg. The reported echocardiographic findings were adjudicated by an independent echocardiographic core laboratory (Asia Cardiovascular Imaging Corelab, Hong Kong, China). The postoperative recovery was uneventful, and without complication. The patient had significant improvement in symptoms and was discharged 4 days after the procedure. At discharge, transthoracic echocardiography confirmed the stability of the devices and the persistent reduction in MR grade (Figure 1e).

At the 1-month follow-up of this patient, MR as assessed by transthoracic echocardiography was graded as mild (Figure 1f) by the echocardiographic core laboratory, and no cardiac-related symptoms or complications were noted.

3 | DISCUSSION

This is the first worldwide implantation of the DragonFly™ transcatheter mitral repair system for treatment of a prohibitive surgical risk patient with DMR. For this initial patient, the procedure was able to be conducted safely with this novel transcatheter mitral repair device, and was able to effectively reduce the MR and achieve an excellent result. The ease of use and outcome in terms of MR reduction are related at least in part to the technological features of the DragonFly™ transcatheter mitral valve repair system which shared the similarity with classic MitraClip and PASCAL system (Table S1). The system has been designed with articulation calibration markers that allows for repeatable and defined manipulation of the delivery system, which aids in surmounting the learning curve associated with mitral valve repair. The independent frictional grasping elements and different sizes of device arms facilitate approaching complex mitral disease, and the central nitinol spacer is designed to effectively reduce MR with less leaflet tension.

Previously, several studies have revealed that the occurrence rate of MR among the Chinese population is similar to that of western countries.[7,8] Unfortunately, the frequency of mitral valve surgery in Chinese patients with MR has been far lower than that which would be expected due to a number of factors, also consistent with a previous studies conducted in Western countries.[9-12] An effective transcatheter mitral valve therapy is therefore warranted to meet this unmet need, particularly in mainland China. While there are a number of different types of transcatheter mitral valve interventions being developed, the transcatheter edge-to-edge mitral valve repair technique has been recommended as a standard treatment option for patients severe symptomatic and high-surgical risk DMR or for those with FMR.[3-5] Results from the MitraClip Asia-Pacific registry also

FIGURE 3 Delivery system of DargonFly™ system. Note the entire delivery system including guiding sheath and device delivery sheath has calibration markers to facilitate the accurate positioning of the clip

show that the transcatheter mitral procedure is effective in reducing MR and has excellent safety outcomes.[12]

In comparison to the Western population, transcatheter mitral repair may be more challenging in the Chinese population due to the relatively smaller left atrial size compared with the Western population.[13] Additionally, more complex mitral valve anatomy such as noncentral regurgitant lesions and a relatively smaller posterior leaflet are common among Chinese MR patients, similar to the patient in this case report.[13] In comparison to the MitraClip transcatheter edge-to-edge repair system, the DragonFly™ transcatheter mitral valve repair system has a central nitinol spacer between the device arms to provide better leaflet coaptation and minimize leaflet stress. The frictional grasping elements have multiple rows of retention elements, which can be independently actuated to grasp either leaflet independently, or both together. The entire delivery system, including guiding sheath and device delivery sheath has unique design calibration markers on both steering, rotation as well as introduction/retrieval, so to facilitate the accurate and interactive positioning of the clip inside heart (Figures 1 and 3). The DragonFly™ device has four different sizes with different arm width and lengths, and each has independent leaflet grasping capability. These design features of the DragonFly™ system have the potential to allow treatment of more complex leaflet pathology safely.

4 | CONCLUSION

This case report demonstrated the initial safety and feasibility of using the DragonFly™ transcatheter valve repair system to treat a prohibitive surgical risk patient with severe DMR. Further study is ongoing to validate this technology.

CONFLICT OF INTEREST

Dr Lim reports consultancy fees from Abbott Vascular, Edwards Lifesciences, Medtronic, and Valgen Medical in addition to chairing the eligibility committees for MitraClip, Pascal, Intrepid and Dragonfly device trials. His institution receives research grants from Abbott Vascular and Edwards Lifesciences. The other authors reported no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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