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Clinical Follow-Up at Half A Year After Transcatheter Tricuspid Replacement

CASE REPORT

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INTRODUCTION

We report a case of a 68-year-old Chinese woman with a replaced metal mitral valve who suffers again from severe tricuspid valve insufficiency. About 15 years ago, the patient had a mechanical mitral valve replacement for severe mitral stenosis via thoracotomy. In July 2021, the patient underwent transcatheter tricuspid valve replacement (TTVR) via the first-generation LuX-Valve system for treating severe tricuspid regurgitation (TR). Six months after TTVR, we compared the changes before and after the transcatheter tricuspid replacement via a heart color ultrasound, chest computed tomography (CT), and chest magnetic resonance imaging (MRI). We found positive changes in the patient after the surgery. In this case, we will expound the current situation of TTVR in China and how this technology has more positive implications for secondary tricuspid disease in the future. Also in postoperative review, after transcatheter tricuspid replacement, we consider that postoperative MRI review has a good effect on the evaluation of the structure and morphology of the transcatheter-replaced valve.

CASE REPORT

In 2006, a 68-year-old female patient was diagnosed with severe mitral stenosis in Shanghai and underwent mechanical mitral replacement via median sternotomy. She was diagnosed with severe TR in July 2021.

Meanwhile, the patient had abdominal distension and a small amount of abdominal effusion before tricuspid surgery, and the preoperative tests showed that the patient had low liver function. Looking at the above factors, we considered it to be associated with the increased vena cava pressure due to severe TR. Preoperative heart color ultrasound (Figure 1) showed the following: after mechanical mitral replacement, no significant abnormality was observed in the mechanical valve function at the mitral valve; left atrium and right heart were enlarged; the interventricular septum moved in the same direction as the left ventricular posterior wall; there was severe TR; the pulmonary systolic pressure was estimated to be 45 mm Hg; there was mild pulmonary hypertension; and left ventricular systolic function decreased. In July 2021, she underwent TTVR via the first-generation LuX-Valve system. The first-generation LuX-Valve system TTVR was performed under general anesthesia and tracheal intubation in the digital subtraction angiography operating room. The patient was slightly tilted on the left side with the right posterior shoulder pad elevated, and a transesophageal ultrasound probe was placed under anesthesia. Through the right lateral fifth intercostal approach, the left femoral artery was separated, a 6F sheath tube was inserted, and a 5F coronary angiography guide wire was inserted for right coronary angiography. Right coronary angiography can be avoided in patients with prior mitral valve replacement when coronary artery disease is excluded. The right atrium was sutured with a double-purse string, and a 6F pigtail tube was inserted for right ventriculography via a double-purse string suture in the center. LuX-Valve was delivered through the right atrium, and the tricuspid annulus was located with the assistance of digital subtraction angiography and transesophageal echocardiography. The valve was released, and the transporter was withdrawn (Video 1). Long-term

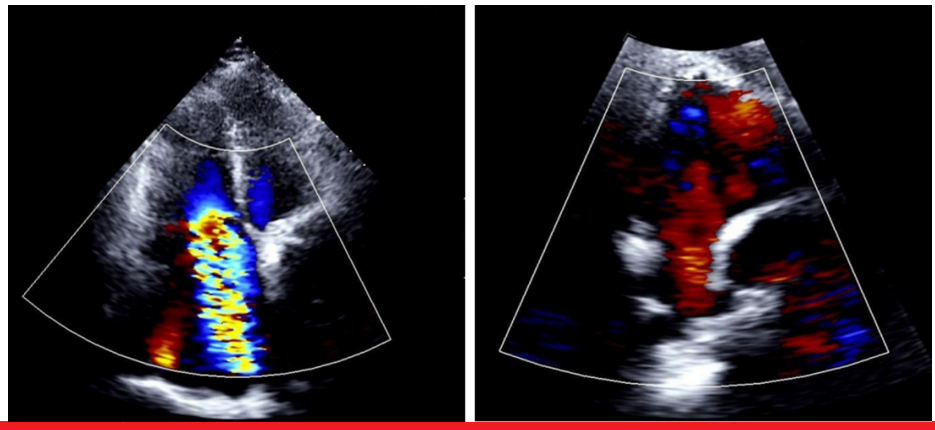

Figure 1. Preoperative heart color ultrasound, in the arteriovenous phase, severe tricuspid regurgitation can be seen.

anticoagulation therapy was prescribed after the operation. At 4 months after the TTVR, heart color ultrasound (Figure 2) showed the following: after mechanical mitral replacement and tricuspid interventional replacement, there was no obvious abnormality in the function of the mechanical mitral; there was no obvious regurgitation after tricuspid replacement; the average tricuspid pressure difference was about 6 mm Hg; right atrium was enlarged; and left ventricular relaxation was reduced. At half a year after the transcatheter tricuspid replacement, chest MRI (Figure 3) showed that postoperative changes of the sternum showed thickening of the surrounding tissues, enlarged heart, after mechanical mitral replacement and tricuspid replacement, and replaced valves are structurally normal. At half a year after the transcatheter tricuspid replacement, chest CT (Figure 4) showed that: changes after cardiac surgery; calculous cholecystitis is suspected; after mechanical mitral replacement and tricuspid replacement; and replaced valves are structurally normal. Comparing the changes before and after transcatheter tricuspid replacement, we find that abdominal distension and liver function are in a better state (Table 1).

DISCUSSION

Surgical correction of secondary tricuspid disease has progressed over the years from primarily conservative treatment to a more liberal approach with the idea of proactively preventing the progression of disease.[1] However, even today, there is no complete agreement on how much a patient can benefit from surgical correction of secondary tricuspid disease or what type of surgery a patient is suitable for. Cardiac surgeons pointed out significant progression of secondary tricuspid disease in long-term follow-up of patients undergoing mitral surgery, increased morbidity, and increased early and late mortality in patients with TR. Tricuspid cycloplasty or repair had the lowest risk of improvement in clinical symptoms, anatomical and hemodynamic changes, and survival.[2-5] But it is worth noting that the long-term effectiveness of conventional tricuspid surgery is not good, and about 40% of patients need retreatment 5-15 years after surgery. The mortality rate of conventional tricuspid surgery is high, and the prognosis is unsatisfactory.[6,7] For patients who have already had transsternal heart valve surgery, a repeat of another transsternal valve surgery will cause damage to the patient's body, the risk of operation is high, and the prognosis will be greatly affected. Minimally invasive transcatheter tricuspid therapy provides a new treatment option for patients with tricuspid disease, and its safety and effectiveness have been confirmed by some studies.[8]

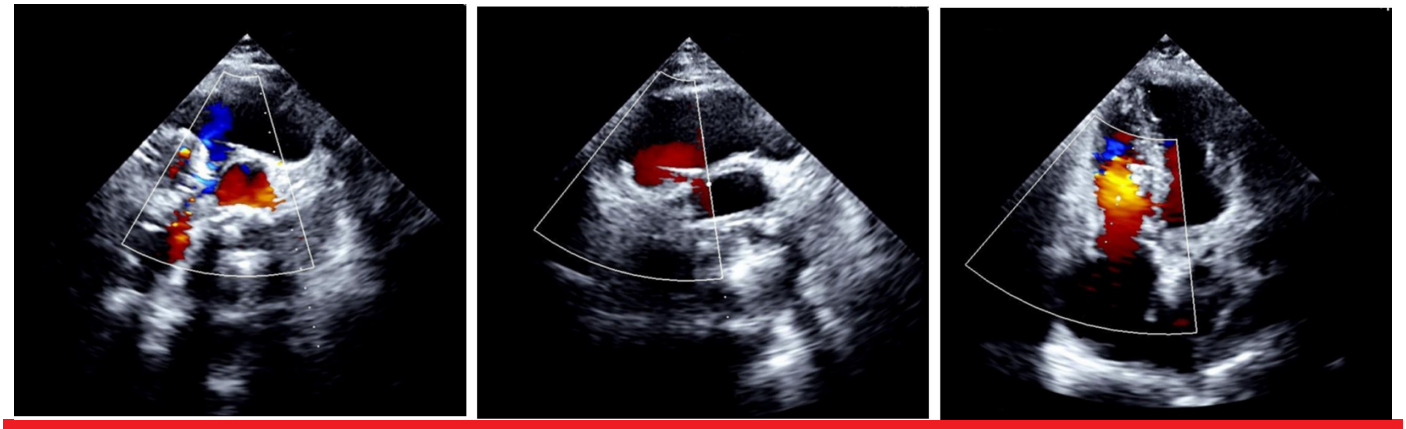

Figure 2. At 4 months after surgery, heart color ultrasound, in the arteriovenous phase, the effective descent of tricuspid regurgitation can be seen.

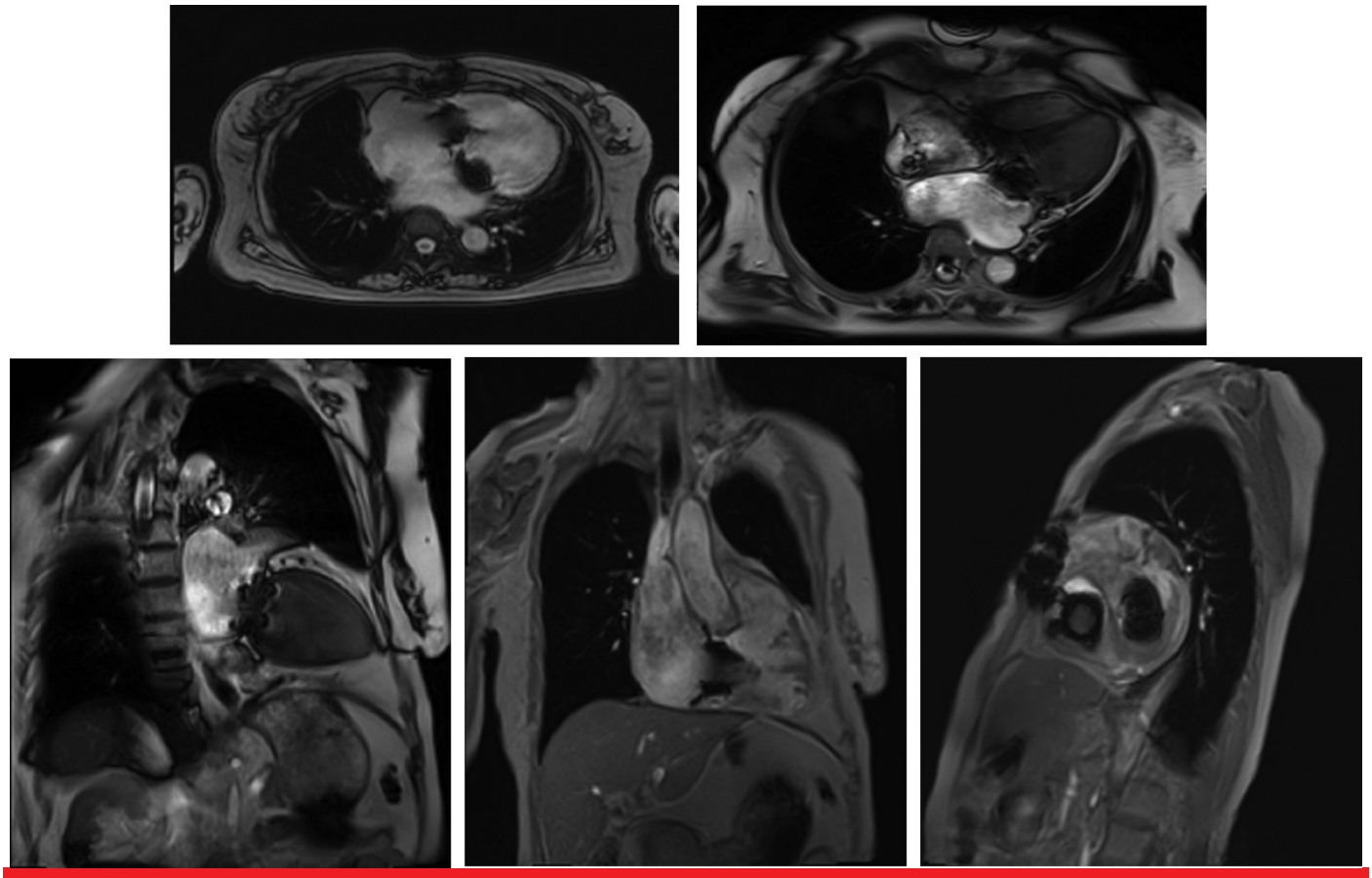

Figure 3. At half a year after surgery, chest MRI. We used chest MRI to review the valve status of patients undergoing tricuspid replacement via transcatheter. As it can be seen, in MRI, the different cross sections of the heart are shown in different shapes and structures.

Let me introduce the status quo of China's autonomous development of minimally invasive transcatheter tricuspid therapy in recent years.

1. **Valvular Leaflet Involution Technique:** The Dragon Fly-T system uses 1 or more clamps to clamp the tricuspid lobes via the femoral vein to reduce regurgitation. The spherical spacer deployed in the center can reduce the central reflux in the flap, and the size of the central spacer can be adjusted according to the needs during the operation to adapt to a variety of anatomical structures, reducing the time to change the type or model of the flap and improving the success rate of the operation.[9]

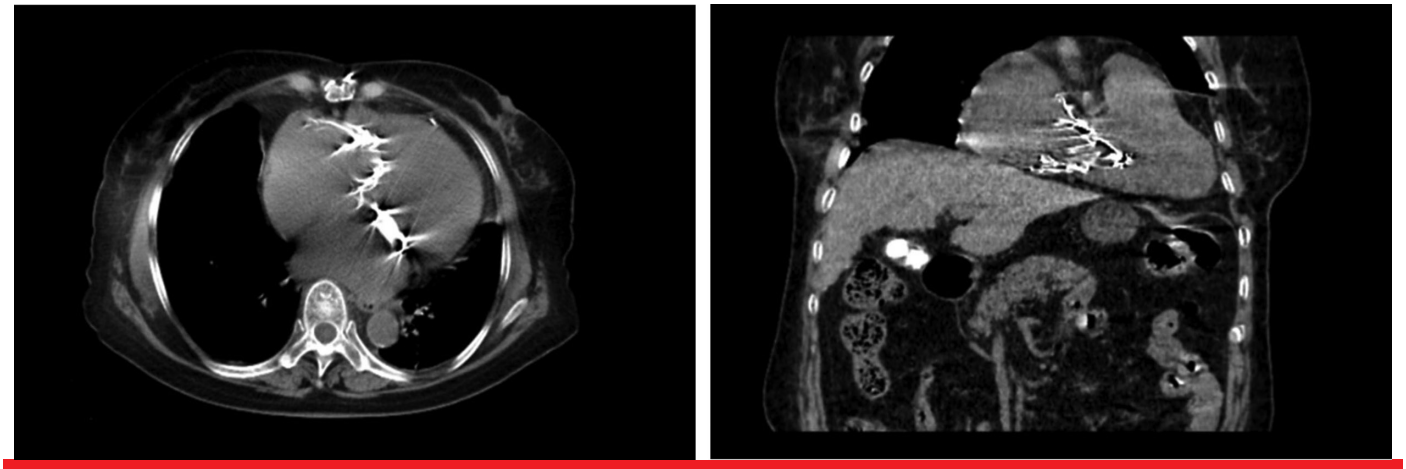

Figure 4. At half a year after surgery, chest CT features show that the shape and structure of the replaced tricuspid haves not changed dramatically, and the structure and position are normal.

Table 1. It is a Great Difference Between Preoperative and Postoperative Liver Function. After Transcatheter Tricuspid Replacement, The Patient's Liver Function Gradually Improved.

Before and After Transcatheter Tricuspid Valve Replacement	Preoperation	Postoperation (After 3 Months)	Postoperation (After Half a Year)
Albumin	25.3 g/L	32.2 g/L	37.1 g/L
Alanine aminotransferase	96 U/L	68 U/L	52 U/L

2. **K-Clip Tricuspid Repair System:** A clamping device is implanted in the posterior tricuspid ring via the jugular approach, reducing the posterior tricuspid ring to reduce the feasibility and safety of TR demonstrated in early animal trials,[10] and K-Clip is expected to be a novel device for valvuloplasty to help patients with severe TR at high surgical risk.[11] The K-Clip, independently developed by China Hui He Medical, imitates Kay's procedure in the way of transcatheter intervention, and the reflux improvement effect is significant. The K-Clip is the only transcatheter valve repair product approved by the CMDE to initiate a registered clinical study in China. A global multi-center registered clinical study has commenced simultaneously in both China and the European Union.
3. LuX-Valve is an in-situ interventional tricuspid replacement device independently developed in China, which is fixed by an anterior valve clamping key and ventricular septal anchoring needle to avoid damage to the structure around the valve ring. Forty-six TR patients who could not receive surgery were included in the preliminary clinical trial, and the success rate of surgery was 97.8%. All the implanted valves were in place, and the mortality rate was 17.4% at the follow-up 6 months after surgery. The remaining 38 patients had a valve in place, and the symptoms of most patients were significantly improved, and peripheral edema and ascites were significantly reduced.[12,13] LuX-Valve is the first TTVR product with completely independent intellectual property rights in China and the most representative one. LuX-valve has been applied in clinical practice and is likely to become the first commercialized TTVR product in the world. The patient mentioned in this case used the first-generation LuX-Valve, and the first-generation LuX-Valve adopts the right atrial path. However, the second-generation LuX-Valve took the right jugular vein path, which will further reduce surgical trauma.

To sum up, these patients with severe tricuspid insufficiency often have high mortality and complications due to terrible somatic conditions and low cardiac function, and the treatment of these patients is an intractable problem in cardiac surgery.[14] Transcatheter interventional treatment of tricuspid lesions, with little trauma, quick recovery, and wide indications– the advantages of this technology in China have developed rapidly in recent years. Existing transcatheter devices for the treatment of tricuspid disease have their own limitations in clinical application, and there is a lack of targeted follow-up evaluation. We think that in this case, for the patient who already had left heart valve surgery and then developed severe tricuspid disease, the adoption of transcatheter tricuspid therapy is constructive. In addition, we found in clinical work that MRI has certain advantages in the review after cardiac valve surgery. Not only does it not require angiogram agents, but it can do fluid imaging. The morphology and structure of the replaced valve were also evaluated more accurately via postoperative MRI examination. We consider that reexamination, especially MRI examination, combined with CT with color doppler echocardiography, is of positive significance for the postoperative comprehensive evaluation of replaced tricuspid. It is hoped to provide some new ideas for auxiliary examinations after cardiac valve operations.

Informed Consent: Written informed consent was obtained from the patient.

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Video 1: Angiography showed that the transcatheter valve was in good position and mobility, without displacement or regurgitation.

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