

Transcatheter Aortic Valve Replacement to Treat a Patient with Levocardia under the Guidance of 3-Dimensional Printing

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Keywords:

Transcatheter aortic valve replacement; Aortic valve; Levocardia; 3-dimensional printing

Abbreviations:

3D: 3-Dimensional; AR: Aortic Regurgitation; AS: Aortic Stenosis; AV: Aortic Valve; CHD: Congenital Heart Diseases; CTA: Computed Tomography Angiography; DSA: Digital Subtraction Angiography; PG: Pressure Gradient; SAVR: Surgical Aortic Valve Replacement; TAVR: Transcatheter Aortic Valve Replacement; TEE: Transesophageal Echocardiography

1. Abstract

A 55-year-old female underwent ventricular septal repair 11 years ago. Symptoms of chest distress and fatigue gradually worsened during the 6-month period before she came to our clinic. Echocardiography showed the continuous integrity of the ventricular septum together with aortic stenosis and aortic regurgitation (the maximum pressure gradient was up to 13 mm Hg). Due to the special anatomical structures and high surgical risk of this patient, we used a 3D printed model preoperatively and intraoperative guidance of digital subtraction angiography to guide the TAVR. Postoperative transesophageal echocardiography showed a significant reduction of the pressure gradient in the aortic valve with no paravalvular leakage. The postoperative 3D printed model showed that the bioprosthesis was well placed. Therefore, TAVR is a feasible method for patients who have levocardia with aortic valve diseases under the guidance of 3D printing.

2. Introduction

Levocardia is one of the heart malformations, and the anatomical structures are complex. The majority of patients with levocardia have partial visceral inversion, atrial inversion, and other complex congenital heart diseases (CHD). Aortic stenosis (AS) and aortic regurgitation (AR) are common heart valve diseases, mostly caused by degenerative and rheumatic aortic valve lesions in older patients [1]. The traditional treatment is surgical aortic valve replacement (SAVR). Due to the need to make a median thoracic incision and to perform the procedure under extracorporeal cir-

ulation, the operating time is longer and the trauma is greater. Meanwhile, lifelong oral warfarin is required for patients after SAVR. For older patients with poor cardiac function, the risks of SAVR are relatively high, and many cannot tolerate it [2]. In recent years, transcatheter aortic valve replacement (TAVR) has become a first-line treatment for patients with severe AS or high surgical risk. The indications have also been gradually extended to patients with low surgical risk [3]. Currently, with the application of 3-dimensional (3D) printing to cardiovascular diseases, the 3D printed model of the aortic root can be used to display the distinct anatomical relationship and make an accurate preoperative plan, thereby providing a novel method of preoperative evaluation for patients before undergoing TAVR [4]. Due to the special anatomical structures and the high surgical risk of this patient, 3D printing was used to simulate and evaluate her condition before TAVR to make sure the operation could be carried out successfully.

3. Baseline Information and Preoperative Imaging

A 55-year-old female had been hospitalized 11 years ago because of recurrent pulmonary infection, and she was finally treated with ventricular septal repair. Six months ago, the patient developed chest distress and fatigue symptoms that gradually worsened. An electrocardiogram showed complete right bundle branch block. The laboratory results showed that NT-proBNP levels reached 2052 mg/L. She was New York Heart Association functional class IV. Echocardiography showed that the patient had an inverted liver and spleen. The areas of the aortic valve (AV) annulus and

left ventricular outflow tract were 606.9 mm² and 704.6 mm² and the diameters of the left-, right-, and non-sinus of Valsalva were 32.3 mm, 26.7 mm, and 31.5 mm, respectively. The areas of the sinotubular junction and the ascending aorta were 718.5 mm² and 834.7 mm², and the angle between the aorta and the annular plane was 77° (Figure 1A-F). The 3D reconstruction of the images taken preoperatively was based on the computed tomography angiography (CTA) data obtained from the patient (Figure 1G). In addition, transesophageal echocardiography (TEE) showed the continuous integrity of the ventricular septum, with AS combining with AR [the maximum pressure gradient (PG) was up to 13 mm Hg; the V_{\max} was 179 cm/s] (Figure 1H). The right atrium and right ventricle were enlarged with severe tricuspid regurgitation.

4. Device Description

A VitaFlow balloon-expandable valve (Microport Medical Co., LTD., Shanghai, China), made of bovine pericardium, was used in the study. The self-expanding nickel-titanium bracket can adapt to the shape of the flap and adapt to the large strain on the shape that occurs during loading and recovery (Figure 2A). The delivery system contains a 16 Fr/17 Fr-equivalent inline catheter sheath, which is more compatible with the coaxiality of the bioprosthesis (Figure 2B). At present, a clinical registration study of VitaFlow is underway to enhance the information about the types of interventional valves independently developed in China and to provide significant treatment methods for older patients with severe valvular disease.

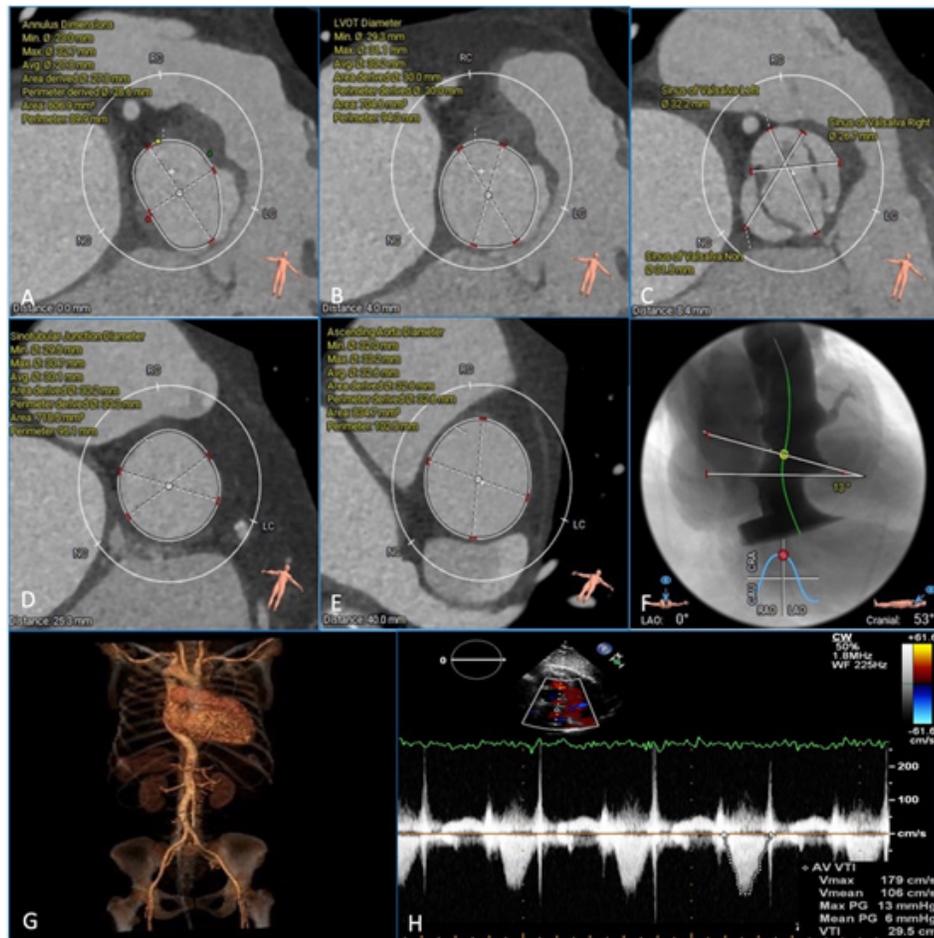


Figure 1. Preoperative imaging of the patient before transcatheter aortic valve replacement to assess the status of the levocardia. (A-F) The areas of the aortic valve annulus and the left ventricular outflow tract were 606.9 mm² and 704.6 mm², the diameters of the left-, right-, and non-sinus of Valsalva were 32.3 mm, 26.7 mm, and 31.5 mm, respectively. The areas of the sinotubular junction and the ascending aorta were 718.5 mm² and 834.7 mm², and the angle between the aorta and the annular plane was 77°. (G) The preoperative 3-dimensional reconstruction was performed according to computed tomography angiography data of the patient, and the levocardia was clearly visible in the figure. (H) Preoperative TEE showed massive regurgitation, and the V_{\max} was as high as 179 cm/s.

5. 3-Dimensional Printed Model and Preoperative Simulation

The DICOM format of the CTA data was imported into Materialise Mimics version 21.0 (Leuven, Belgium) software, and the threshold segmentation function was used to segment the 3D reconstructed model of the aortic root. The 3D model of the aortic root was extracted, trimmed, smoothed, and repaired digitally so that the structures of the aortic root, the morphology of the leaflets, and the distribution of the calcification were restored in a 1:1 ratio (Figure 2C). The Standard Tessellation Language files of the 3D reconstructed model were exported to a Stratasys Polyjet 850

multimaterial full-color 3D printer. Different tissues of the aortic root were edited and printed with materials of different degrees of hardness and different colors to obtain the 3D printed model of the aortic root (Figure 2D-F). The main steps of TAVR were simulated during the bench test (Figure 2G, H). The preoperative 3D printed model was simulated on the bench test, so as to complete the simulated procedures of TAVR (including femoral artery approach, coaxial adjustment of the delivery system, positioning and balloon expansion, etc.). After several simulations completed, the size of bioprosthesis and the procedural strategy were determined.

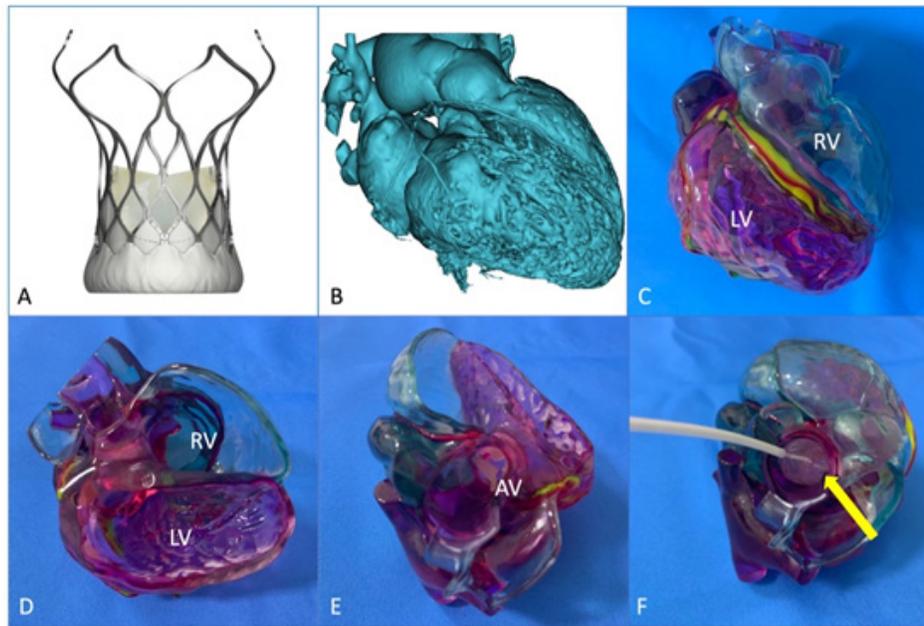


Figure 2. The VitaFlow balloon-expandable valve (Microport Medical Co., LTD., Shanghai, China) and the preoperative simulation. (A) The transcatheter VitaFlow bioprosthesis. (B) 3-Dimensional reconstruction of levocardia using the patient's computed tomography angiography data. (C-E) The 3-dimensional printed model of the patient. The aortic stenosis could be seen clearly from the multicolor model. (F) The simulated expansion to choose the size of the bioprosthesis. The yellow arrows show the appropriate position of the balloon.

6. Procedural Steps

Under the guidance of digital subtraction angiography (DSA) and TEE, the left femoral artery was selected as the puncture point. After a successful puncture, the patient was given local anesthesia with 2% lidocaine; a 6 Fr arterial sheath was placed, and 3000 U heparin was injected intravenously. DSA of the noncoronary sinus showed that the patient had AS combined with AR and AV calcification; the left and right coronary arteries were unobstructed. The right femoral artery was punctured and a 6 Fr femoral sheath was inserted. DSA of the right femoral artery showed good filling and a normal diameter. Then, the 9 Fr Cook sheath was replaced; a 6 Fr pigtail catheter and the loach guide wire were inserted into the ascending aorta, and the loach guide wire was replaced by the Lunderquist guide wire. The 22 Fr sheath was placed in the femoral

artery along the supporting guide wire. The pigtail catheter was used to guide the 1.5-m loach guide wire through the AV annulus. The loach guide wire was exchanged with the 6 Fr pigtail catheter into the apex of the heart. The left ventricular pressure was 130/25 mm Hg, and the ascending aorta pressure was 145/45 mm Hg. A 2.6-m Lunderquist guide wire was inserted into the left ventricle. After preoperative CTA assessment, a 30-mm VitaFlow balloon-expandable valve was selected, and the delivery system was delivered into the AV along the Lunderquist guide wire (Figure 3A). Afterwards, the pacing reached 180 beats/min, and the bioprosthesis was released successfully (Figure 3B, C). Intraoperative DSA showed that the position of the bioprosthesis was ideal, the PG dropped to the normal range, and TEE showed the same results as DSA without paravalvular leakage (Figure 3D, E).

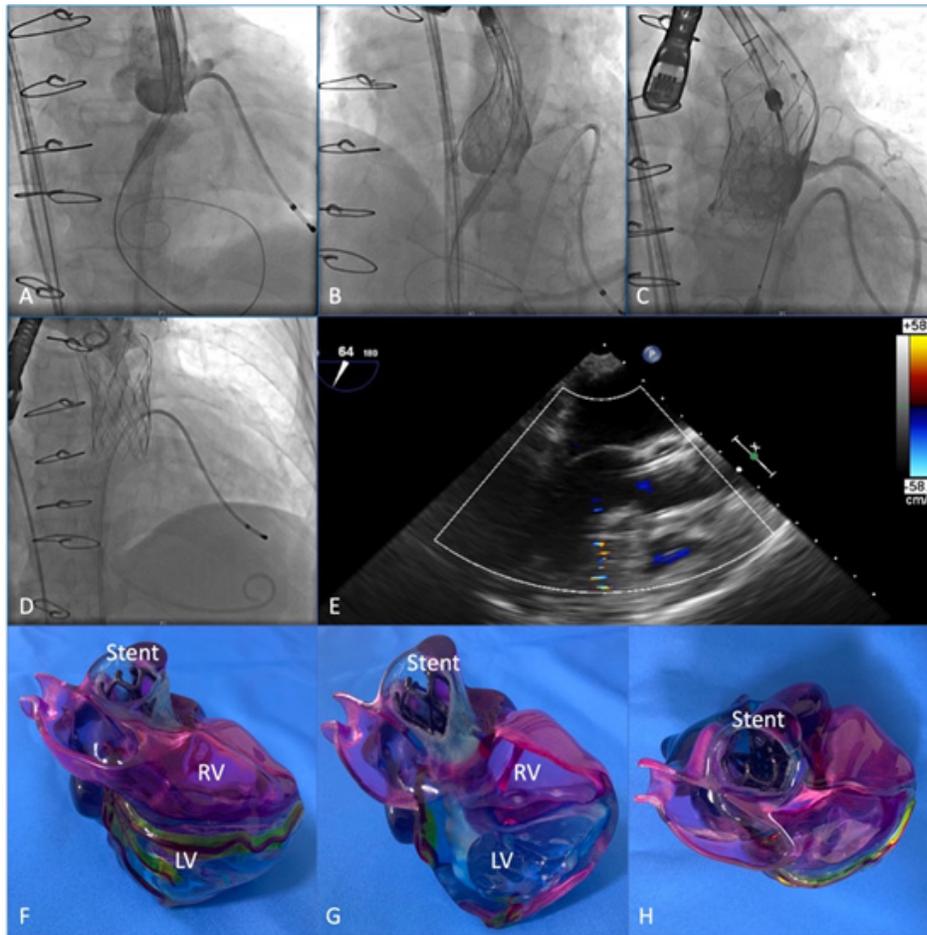


Figure 3. The intra- and postoperative digital subtracted angiography and transesophageal echocardiography images showing the process and the immediate result of procedures. (A) The delivery system was delivered into the aortic valve along the Lunderquist guide wire. (B) The stent began to expand. (C) The stent was fully expanded after the balloon expansion. (D-E) The immediate digital subtracted angiography and transesophageal echocardiography images showed the appropriate position of the stent and no regurgitation in the aortic valve. (F-H) The postoperative 3-dimensional printed model verified the position of the stented valve. LV: left ventricle; RV: right ventricle.

7. Hospitalization Outcomes

The patient recovered well and was transferred from the intensive care unit to the ward 2 days after TAVR and was discharged after another 4 days. TEE before discharge showed that the V_{max} was 179 cm/s, PG_{max} was 11 mm Hg, and PG_{mean} was 3 mm Hg. The postoperative 3D printed model verified the ideal position and shape of the stent by using postoperative CTA data, which was consistent with the results of intraoperative DSA and TEE (Figure 3F-H).

8. Discussion

Levocardia is an extremely complex condition characterized by a mirror-image reversal of the viscera relative to the normal position and the right apex of the heart. In most patients, it is associated with CHDs. As a heart malformation with complex anatomical structures, levocardia is difficult to treat surgically. Per a recent report, the incidence is 1 in 22,000 in the general population and is about 0.4% to 1.2% in all patients with CHDs [5]. Studies have suggested that levocardia is associated with other complex extra-cardiac malformations [6]. Anselmi et al. suggested that levocardia

occurred with visceral inversion, that is, the lobules of the liver, the superior and inferior vena cava, and the right atrium were on the left, and the heart apex was towards the right [7]. Up to 95% cases of levocardia are associated with cardiac malformations, such as right ventricular outflow tract obstruction, ventricular septal defect, and an inverted and displaced heart cavity [8]. The underlying pathogenesis of levocardia is not fully understood. This condition may be diagnosed by taking a detailed history and performing a physical examination, electrocardiograms, and cardiac imaging [6]. Furthermore, patients with levocardia often have significant cardiac abnormalities and thus have a shorter life expectancy. Only 5 to 13% of patients survive more than 5 years, which is related mainly to the severity of the cardiac abnormalities [6]. Today, the preoperative evaluation of TAVR is of great significance for the successful implementation of the treatment and the long-term quality of life of the patients. Preoperative evaluation is done mainly to determine the severity of the AV, the surgical risk, the surgical contraindications, and at the same time to select the appropriate bioprosthesis and evaluate the best surgical approach. Because the anatomical structures of the aortic root cannot be observed directly

during TAVR, evaluation of the preoperative images is crucial. In the 1990s, researchers at the Massachusetts University of Technology pioneered 3D printing technology, which converted digital signals into physical models with the needed physical characteristics using metals, polymer materials, and photosensitive resin. The models were created from information communicated from computers to 3D printers [9]. In recent years, 3D printing has also been applied to the treatment of cardiovascular diseases, showing positive effects when used in the preoperative evaluation of patients needing operations for complex CHDs, heart tumors, aortic dissection, and other diseases [4]. Schmauss et al. produced a 3D printed evaluation of a patient with severe porcelain AV before TAVR in 2012 and achieved successful results [10]. At present, 3D printing may accurately display the anatomical structures to assess possible complications. At the same time, 3D printed models can be used for preoperative simulations, which play an important role in the preoperative evaluation of patients indicated for TAVR [11]. We used 3D printed models created for this patient with levocardia to intuitively display the anatomical structures, to accurately measure the size of the AV annulus, and to accurately select the matching bioprosthesis. In addition, the preoperative 3D printed model of the patient is used to simulate his or her condition during the bench test, to become familiar with the surgical approach, shorten the operation time, reduce the DSA time and amount of radiation, and effectively improve the success rate of TAVR as well, which is of great significance for patients with special anatomical structures.

9. Conclusion

We describe a patient with levocardia who had AS combined with AR and who was treated with TAVR with the preoperative guidance of 3D printing. The postoperative PG was significantly reduced and no paravalvular leakage was observed. The postoperative 3D printed model showed that the stent was well placed, suggesting that 3D printing technology played an important role in TAVR and has broad clinical prospects.

10. Funding

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of Xijing Hospital (Approval Number: KY-20192138-C-1) and ClinicalTrials.gov Protocol Registration System (NCT02917980).

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