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CASE REPORT

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The first transapical transcatheter aortic valve-in-valve implantation using the J-valve system into a failed biophysio aortic prosthesis in a patient with high risk of coronary obstruction

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Abstract

We report the first successful valve-in-valve (ViV) implantation into a failed Edwards Biophysio surgical prosthesis (Edwards Lifesciences, Irvine, CA) and also the first use of the J-Valve system (Jie Cheng Medical Technologies, Suzhou, China) in a ViV configuration. A 77-year old male had symptomatic severe aortic stenosis secondary to failure of a 25 mm Biophysio bioprosthetic valve implanted 11 years previously, along with concomitant coronary artery bypass grafting. Transthoracic echocardiography (TTE) revealed calcified leaflets, a mean aortic gradient of 50 mm Hg, and an estimated valve area of 0.9 cm^2 with no aortic insufficiency. The patient had low coronary ostial height with the right coronary artery arising only 8.5 mm from the valve annulus and the left main coronary artery arising only 9.4 mm from the valve annulus. Risk of coronary ostial obstruction was especially concerning in context of both the patient's extremely low coronary ostial height and the unique structure of the Biophysio valve. Under general anesthesia, transapical transcatheter aortic ViV implantation with a 25 mm J-Valve was performed in a hybrid operating room. The J-Valve prosthesis was deployed in the 25 mm Biophysio surgical valve without difficulty or complications. There were no intraoperative or postoperative complications. The patient was discharged home after 3 days. TTE at 1 year showed a mean aortic valve gradient of 14 mm Hg, and no aortic insufficiency. This case demonstrated that J-Valve implantation may be a new option for patients at high risk for coronary obstruction.

KEYWORDS

aortic valve, biophysio valve, J valve, TAVI, valve-in-valve

1 | INTRODUCTION

The indication for transcatheter aortic valve implantation (TAVI) is ever expanding to include moderate risk patients. As the population ages, an increasing number of patients with failed bioprosthetic aortic valves will be referred for re-operative valve surgery. Valve-in-valve implantation (ViV) is a promising alternative to re-operative surgery but poses unique challenges, which are specific to the characteristics of some types of failed bioprostheses [1–3]. We report the first successful ViV implantation into a failed Edwards Biophysio surgical prosthesis (Edwards Lifesciences, Irvine, CA) and also the first use of the J-Valve system (Jie Cheng Medical Technologies, Suzhou, China) in a ViV configuration.

The Edwards Biophysio surgical bioprosthesis has a unique design, which is very different from other surgical tissue valves (**Figure** 1). This unique bioprosthetic aortic valve has a flexible nitinol annular ring with tall flexible struts and leaflets, and is sutured directly into each aortic commissure in a supra-annular position [4]. Therefore, both left and right coronary ostia are usually below the top end of the struts and leaflets, and the risk for coronary ostial obstruction is very high with ViV implantation (**Figure** 2). To date there have been no reported cases of ViV therapy for a failed Biophysio prostheses.

The J-Valve is a new generation of self-expanding low-profile transcatheter porcine valve that is designed to be delivered transapically. The porcine valve is mounted annularly on the valve stent. The

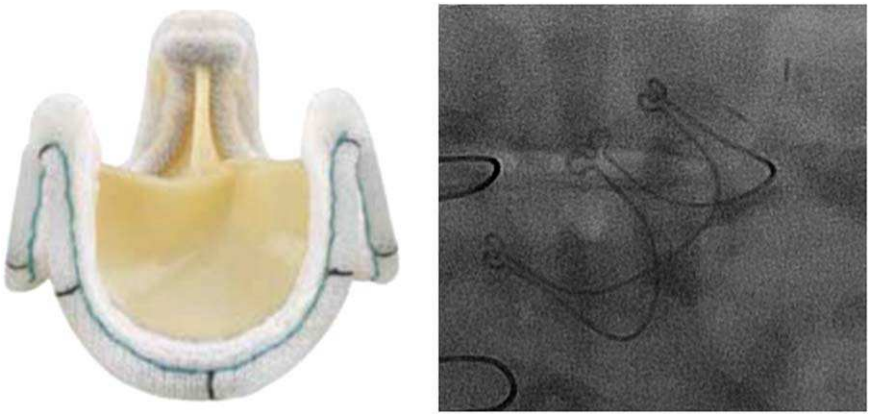

FIGURE 1 Edwards Biophysio pericardial tissue valve and fluoroscopy of the valve frame [Color figure can be viewed at wileyonlinelibrary.com]

feasibility of the J-valve system for use in either aortic regurgitation or stenosis has been reported in previous studies and the early outcomes were encouraging [5–8]. The J-valve system features a unique 2-piece structure that consists of a 3-prong clasper and a support frame connected to each other with three stitches (**Figure** 3). The claspers are placed into the sinuses of Valsalva and aid in positioning the valve. More importantly, when deployed the claspers secure the leaflets into the valve complex providing additional nonradial fixation of the leaflets. This feature is critical as coronary obstruction at the time of VIV implantation is generally because of the leaflets of the failed prosthesis protruding into the sinus of Valsalva. Securing the leaflets of the failed prosthesis into the J-Valve implant may decrease the risk of coronary obstruction.

2 | CASE

A 77-year old male had symptomatic severe aortic stenosis secondary to failure of a 25 mm Biophysio bioprosthetic valve implanted 11 years

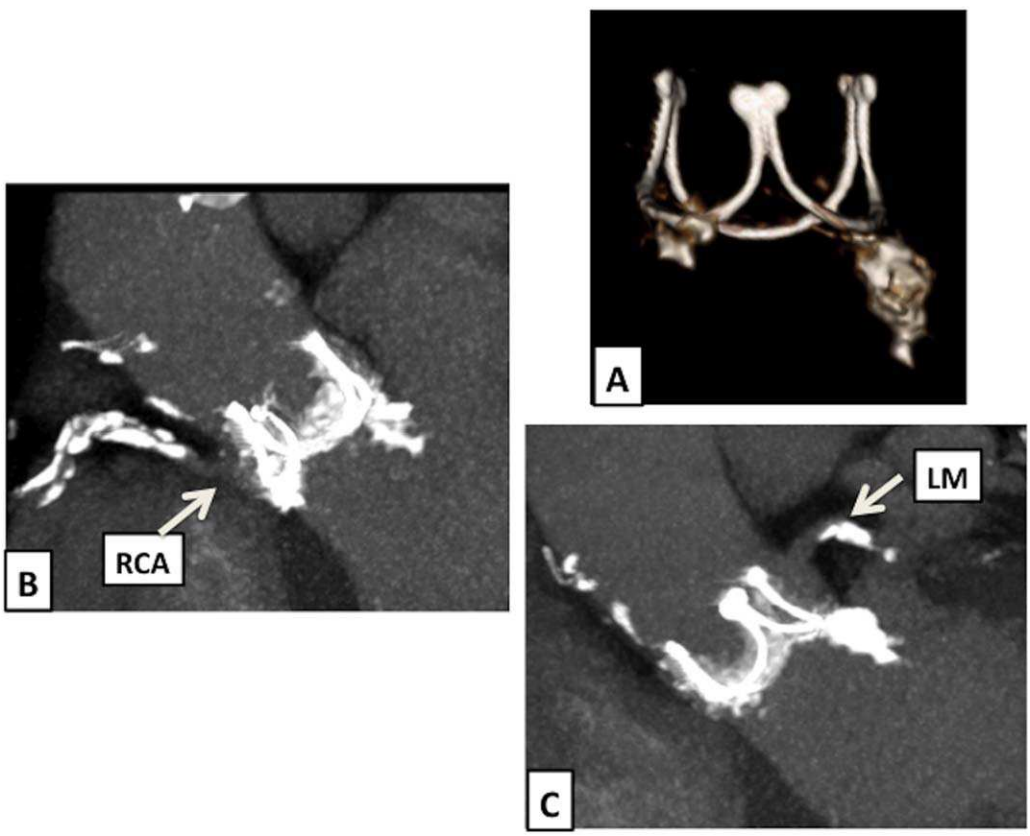

FIGURE 2 A, CT of the frame of the failed Biophysio valve and its relationship with B, right and C, left coronary ostia [Color figure can be viewed at wileyonlinelibrary.com]

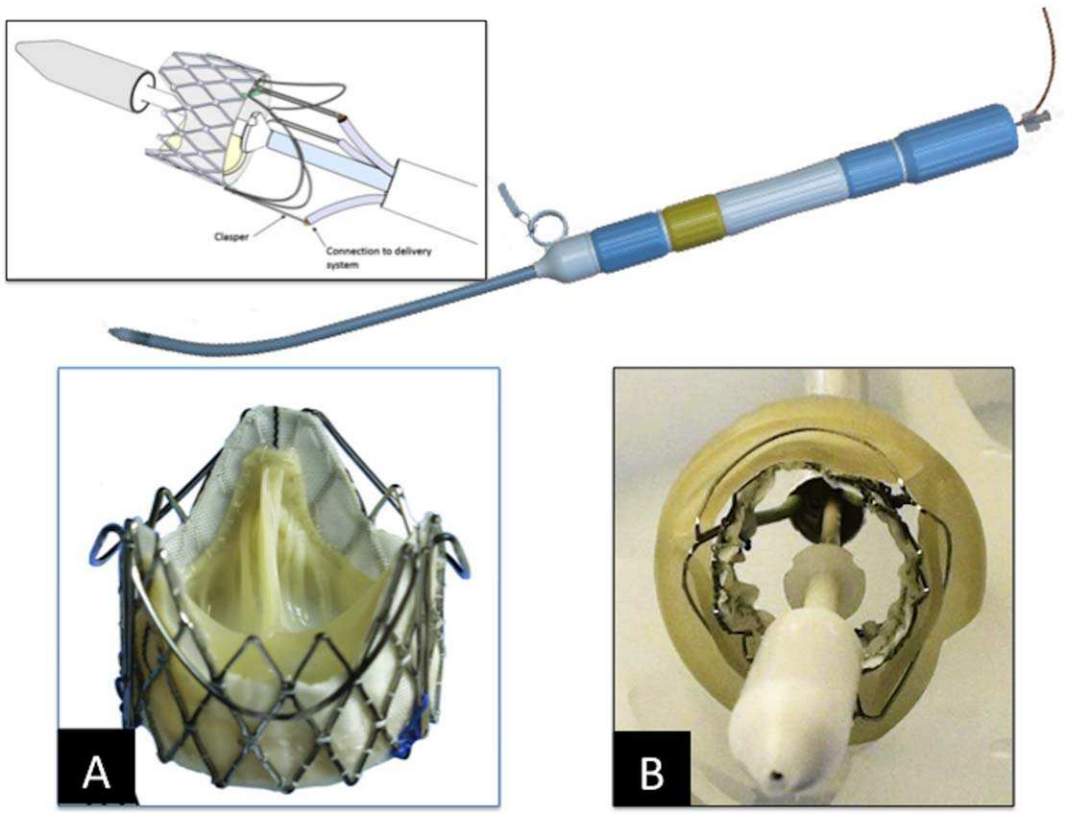

FIGURE 3 A, J-Valve; B, Ausper delivery system, and in vitro implant (native or surgical leaflets embraced between three claspers and valve stent) [Color figure can be viewed at wileyonlinelibrary.com]

previously, along with concomitant coronary artery bypass grafting. Transthoracic echocardiography (TTE) revealed calcified leaflets, a mean aortic gradient of 50 mm Hg, and an estimated valve area of 0.9 cm^2 with no aortic insufficiency. Ventricular function was normal with a left ventricular ejection fraction of 60%. The patient had low coronary ostial height with the right coronary artery arising only 8.5 mm from the valve annulus and the left main coronary artery arising only 9.4 mm from the valve annulus. The VTC revealed the RCA distance of 2.5 mm and LM distance of 6 mm. The sinus-tubular junction (STJ) height was 14 mm while the height of the surgical valve struts 19 mm. Risk of coronary ostial obstruction was especially concerning in context of both the patient's extremely low coronary ostial height and the unique structure of the Biophysio valve (**Figure** 2). As such, the patient was deemed not to be a suitable candidate for our commercially available transcatheter valves. A transcatheter, as opposed to open surgical, approach was selected as the patient refused another open-heart surgery and surgical risk was relatively high in the setting of prior surgical intervention and a patent bypass graft.

Under general anesthesia, transapical transcatheter aortic ViV implantation with a 25 mm J-Valve was performed in a hybrid operating room. The J-Valve prosthesis was deployed in the 25 mm Biophysio surgical valve without difficulty or complications (**Figure** 4). A routine left mini-thoracotomy and left ventricular apical sutures were utilized for the operation. A pigtail catheter was inserted via a femoral artery. Heparin was given to achieve PTT of >300. An extra-stiff guidewire was used. Pre-implant balloon aortic valvuloplasty with a 20 mm balloon was performed because of severe stenosis. The sheathless delivery system was inserted into the left ventricle and advanced under fluoroscopic guidance to position above the Biophysio valve (**Figure** 4**A**). The three U-shape claspers were completely deployed and were pulled down to make sure the three claspers were inside the aortic sinus, embracing the Biophysio valve leaflets (**Figure** 4**B**). After the correct position was confirmed by both fluoroscopy as well as TEE, the valve was brought down to position (**Figure** 4**C**). The valve was then deployed without rapid ventricular pacing (**Figure** 4**D**,**E**). Postimplant dilation with a 24 mm balloon was performed to achieve a full expansion of the valve stent. Aortic root angiography revealed no aortic insufficiency and no paravalvular leak with patent coronaries and good valve-in-valve position (**Figure** 5**A**). Transesophageal echocardiography showed normal function of the J-Valve with a mean transaortic pressure gradient of 11 mm Hg and no aortic insufficiency or paravalvular leak (**Figure** 5**B**). There were no intra-operative complications. The patient did well postoperatively and was extubated 3 hours after the procedure and discharged home after 3 days. The patient had an underlying first degree atrioventricular block with a pre-operative PR interval of 284 ms which improved to 258 ms prior to discharge. TTE at discharge showed an aortic valve area of 1.7 cm^2 with a mean gradient of 16 mm Hg and TTE at 1 year showed a mean aortic valve gradient of 14 mm Hg, no aortic insufficiency, trivial mitral and tricuspid regurgitation, and normal biventricular function. At 1-year follow-up

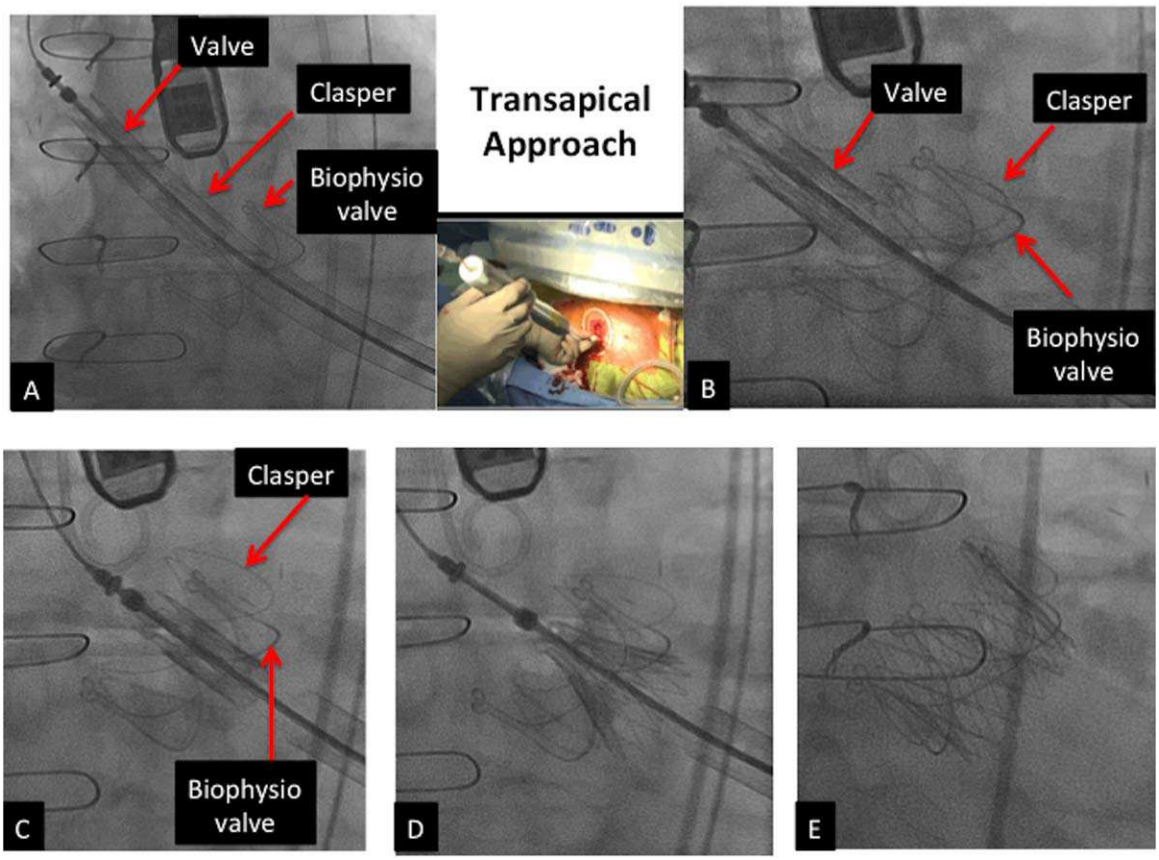

FIGURE 4 Steps of implantation of J-Valve using transapical approach. A, Advancing the delivery system above the Biophysio surgical valve; B, three J-Valve claspers positioned in three sinuses; C, J-Valve in the appropriate position; D, partial deployment of J-Valve; E, full deployment of J-Valve [Color figure can be viewed at wileyonlinelibrary.com]

the patient was doing well and asymptomatic in New York Heart Association class I and Canadian Cardiovascular Society class 0. There were no postoperative complications up to 1-year follow-up.

3 | DISCUSSION

Although open-heart re-do aortic valve replacement remains the standard therapy for failed prosthetic valves and can be performed with clinically acceptable operative mortality and morbidity in many patients, there are some patients with prosthetic dysfunction/degeneration who are either elderly or at high risk for reoperation in terms of mortality and/or morbidity [9,10]. Good early and mid-term outcomes of transcatheter aortic ViV into failed surgical bioprostheses have been demonstrated by us and others [1,11–14].

Left main occlusion is a potentially fatal complication of TAVI, and may be even more common in association with aortic ViV implantation. The size of sinus of Valsalva, the height of a coronary ostium related to the height of a surgical bioprosthetic leaflet, and the bulk of a surgical

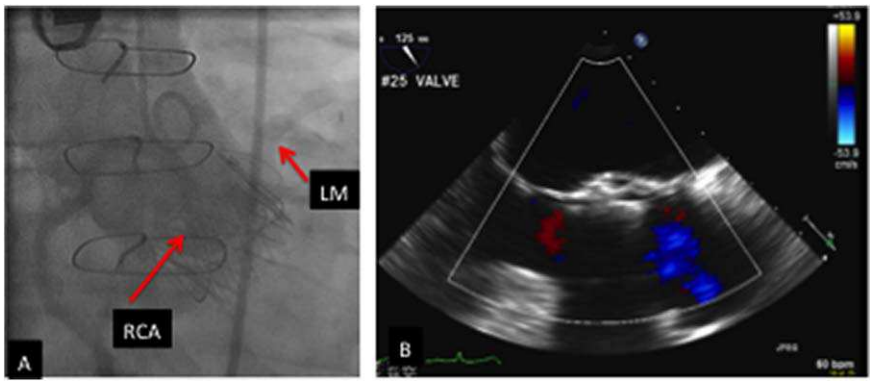

FIGURE 5 A, Postimplantation aortography and B, TEE, showing patent RCA and left main, as well as no aortic insufficiency or paravalvular leak [Color figure can be viewed at wileyonlinelibrary.com]

bioprosthetic leaflet are the major determinants of the risk for coronary ostial obstruction. Generally speaking, stentless bioprosthetic valves or those that are internally stented (e.g., Mitroflow and Trifecta) may be at a slightly higher risk, as the leaflets of these surgical valves can extend outward in a tubular fashion following ViV implantation [15]. The strategy of grasping the aortic valve leaflets to prevent left main obstruction has been reported with variable success with the use of JenaValve and Medtronic Engager valve [16,17]. Other potential strategies to prevent coronary obstruction during ViV implantation include preventive coronary artery stenting [18], and bioprosthetic or native aortic scallop intentional laceration (called BASILICA, presented by Dvir et al. at TCT 2017) prior to TAVI or ViV. In our experience, a number of patients referring for ViV are declined for the procedure because of the risk of coronary obstruction. In this case, the risk for coronary ostial obstruction is high with ViV implantation into the Edwards Biophysio surgical valve, which has a flexible nitinol annular ring with tall flexible struts and leaflets. The uniquely designed J-Valve has three claspers, which correspond to the three cusps of a native aortic valve or surgical bioprosthesis and secure the cusps into the valve complex providing additional nonradial fixation of the cusps and potentially preventing coronary obstruction. Therefore, this valve, which is unlike other currently available transcatheter valves, can be used for noncalcified aortic valves [5–8] and is probably feasible for aortic valves or bioprosthetic valves at the risk of coronary ostial obstruction as demonstrated in this case. The J-Valve was designed for both TF and TA approach. At this point, TA system has been approved for both AS and AI patients in China. Transfemoral system will be available for first in human in the near future. Relative to TF approach, TA is more invasive, particularly requiring general anesthesia and mini-thoracotomy.

In this case, a 25 mm J-valve was implanted into the 25 mm surgical valve and therefore, the J-valve with annularly mounted porcine valve was likely not fully expanded because the internal diameter of the surgical valve is smaller than 25 mm. This may explain the relatively high mean transaortic pressure gradient (14 mm Hg) at 1-year follow-up. This situation has also been observed in aortic ViV cases using other transcatheter valves with annularly mounted leaflets, such as JenaValve and Sapien valve. The average of mean transaortic pressure gradients following ViV implantation into 25–29 mm surgical valves with Sapien valves was 15.8 ± 6.2 mm Hg [1].

4 | CONCLUSION

We describe the first successful ViV implantation of the J-Valve to treat failed surgical bioprosthesis as well as the first successful treatment of the failed Biophysio prosthesis using a ViV approach. This case demonstrated that J-Valve implantation may be a new option for patients at high risk for coronary obstruction.

CONFLICT OF INTEREST

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