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VALVULAR HEART DISEASE

Original Studies

First Percutaneous Transcatheter Aortic Valve-in-Valve Implant With Three Year Follow-Up

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Objectives: This study was conducted to report the clinical, hemodynamic, and iconographic outcomes of the longest survivor of the global CoreValve experience. Background: Early results of percutaneous heart valve (PHV) implantation for severe symptomatic aortic stenosis (AS) have been encouraging, with mid term survival up to 2 years; however longer durability term is unknown. Although a PHV has been implanted in a degenerated surgical bioprosthesis, the feasibility of a PHV-in-PHV has not been demonstrated. Methods: A patient with severe refractory heart failure due to severe aortic regurgitation (AR) and moderate AS, underwent CoreValve prosthesis implantation. The PHV was deployed too proximal into the left ventricular outflow tract, resulting in severe AR through the frame struts. Using the first PHV as a landmark, a second CoreValve was then deployed slightly distal to the first, with trivial residual paravalvular leak. Results: The second CoreValve expanded well with proper function. Transvalvular gradient was 8 mmHg. Both coronary ostia were patent. New mild to moderate mitral regurgitation occurred due to impingement of the anterior mitral leaflet by the first PHV. NYHA functional class improved from IV to II, maintained over the past 3 years. Echocardiography at 3 years showed normal functioning CoreValve-in-CoreValve prostheses, without AR or paravalvular leaks. Transvalvular gradient was 10 mmHg. Cardiac CT showed stable valve-in-valve protheses with no migration. Conclusion: The CoreValve prosthesis has maintained proper function up to 3 years, with no structural deterioration or migration. Treating mixed aortic valve disease with predominant AR is feasible. The concept as well as durability of the first PHV-in-PHV has also been demonstrated. © 2008 Wiley-Liss, Inc.

Key words: VALV – valvular heart disease; aortic valve; stenosis; percutaneous; prosthesis

INTRODUCTION

Percutaneous heart valve (PHV) implantation in the aortic position is a novel technique that was first performed by Cribier et al. in 2002 [1]. This technology offered patients with severe symptomatic aortic stenosis (AS) and high surgical risk for aortic valve replacement (AVR) an alternative modality of treatment. Several groups have reported their experiences with both the balloon expandable and self expandable technologies, and early results have been encouraging [2–4], with mid term survival up to 2 years. The longer term durability of the PHV, however, is still uncertain at this time. Besides implantation of PHVs in native AS, the valve-in-valve concept—where a PHV was implanted in a degenerated surgical bioprosthesis—has also been reported in 2007 [5].

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Conflicts of interests: Drs. Carlos E. Ruiz and Jean C. Laborde are consultants for CoreValve, and Jean C. Laborde is now an employee of CoreValve.

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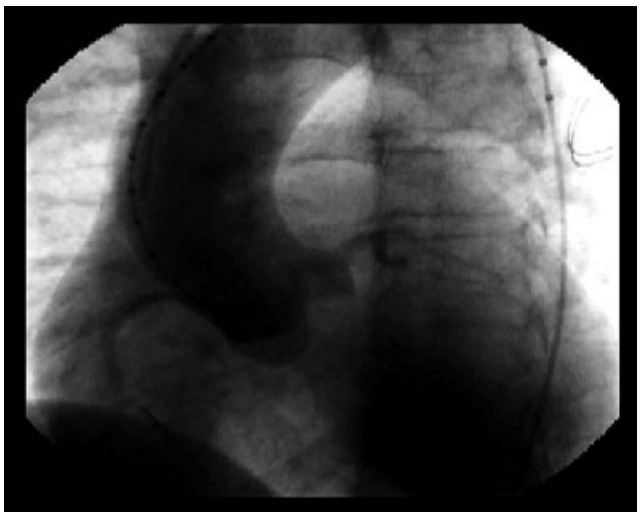

Fig. 1. Aortogram showing contrast in the left ventricle (LV) after 1 beat.

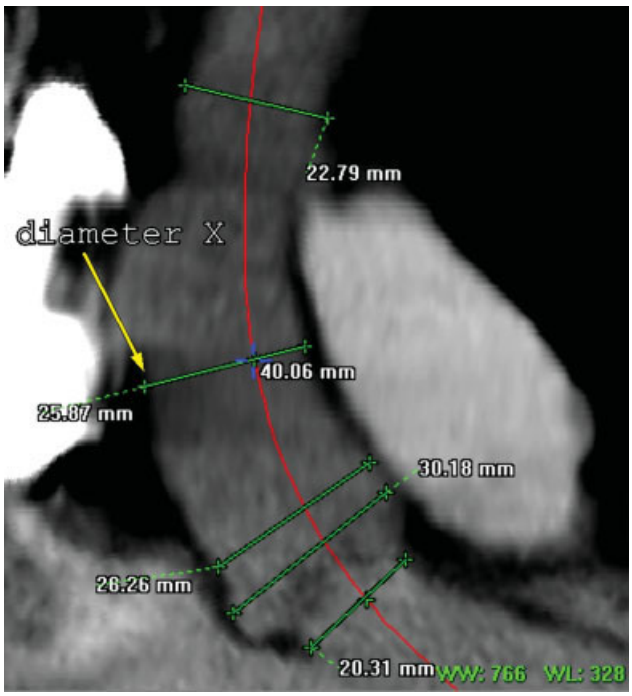

Fig. 2. CTA measurements of the aortic annulus and ascending aorta.

This study was conducted to report the clinical, hemodynamic, and iconographic outcomes of the longest term survivor of the global CoreValve experience. Furthermore, this is the first patient who experienced placement of two CoreValve implants during the same procedure, constituting the first valve-in-valve implantation.

METHODS

Study Design

This study was conducted to assess the long term functional and clinical performance of the first percutaneous valve-in-valve implantation.

Patient

A 58-year-old female was admitted for severe congestive heart failure (CHF). Past medical history was significant for hypertension, chronic atrial fibrillation, and rheumatic heart disease.

Echocardiography showed mixed aortic valve disease with severe aortic regurgitation (AR) (grade 4+) and moderate AS (Fig. 1). Peak systolic velocity was 3.4 m/sec and mean pressure gradient (MPG) was 26 mmHg. The aortic annulus measured 20 mm (Fig. 2). There was trivial mitral regurgitation (MR) and the mitral valve area (MVA) was 2.4 cm^2. Left ventricular ejection fraction (LVEF) was 40%.

Surgical AVR was recommended but the patient flatly refused the procedure despite repeated advice and counseling of both the cardiologist and cardiothoracic surgeon. She remained in NYHA class IV despite maximal medical therapy, and as an alternative option, the percutaneous route of aortic valve implantation was offered after having the case reviewed and approved by the institutional review board. The experimental nature of this treatment was fully explained and the patient agreed to undergo this novel treatment with complete knowledge of the risks involved.

CoreValve Prosthesis

This PHV consists of a tri-leaflet bioprosthesis made of bovine pericardium mounted and sutured in a self expanding nitinol frame [6]. Its corresponding effective valve diameter is 22 mm. The frame is 50 mm in total length, with the lower (inlet) portion having a high radial force to expand into the calcified aortic leaflets and annulus; the middle portion carries the valve leaflets (supra-annular valve function) and is constrained to avoid obstructing the coronary arteries; and the upper portion (outlet) is flared wide to fix the device in the ascending aorta and assure proper orientation to the blood flow. The first generation 25F delivery system was used in this study.

Procedure

The procedure took place in February 2005. The patient was brought to the catheterization laboratory and placed under general anesthesia. Surgical cutdowns of the left iliac artery and left iliac vein were performed for extracorporeal circulation support. Surgical cutdown was also performed on the right iliac artery for a 25F delivery system access. A pigtail catheter was advanced through a transradial route and root aortogram, left ventriculogram and hemodynamic record-

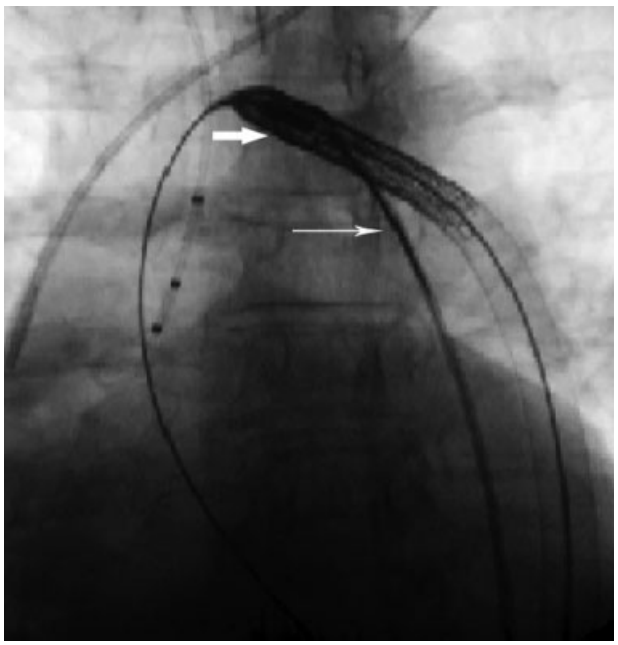

Fig. 3. Thick arrow indicates CoreValve delivery system. Thin arrow indicates snare.

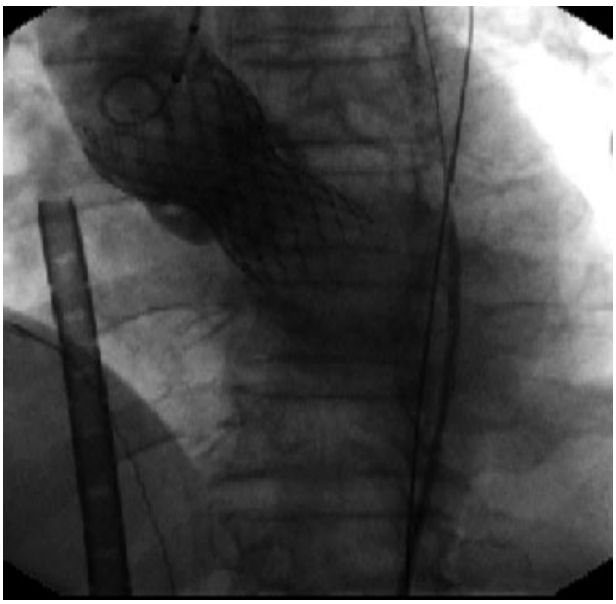

Fig. 4. Post initial PHV deployment aortogram showing contrast in the LV after 1 beat.

ings showed 4+ AR and moderate AS in concordance with the findings on echocardiography.

The aortic valve was crossed retrograde using standard technique. The CoreValve prosthesis was immersed in ice cold saline and loaded into the delivery system. The delivery system was introduced through the right iliac artery, and was advanced with the support of a Gooseneck snare, around the aortic arch and into the ascending aorta (Fig. 3). The patient was placed on complete extracorporeal circulation at that point and the delivery system was further advanced across the noncalcified aortic valve over an extra stiff Amplatz wire. The deployment of the PHV was continuously monitored by intracardiac echocardiography (ICE), and by occasional contrast injections through the pigtail catheter in the ascending aorta since there was no calcified landmarks available. The PHV was however, inadvertently deployed too proximal into the left ventricular outflow tract (LVOT), resulting in severe aortic regurgitation through the frame struts (Figs. 4 and 5). As the patient did not consent for surgery, the surgical bail-out was not an option. Therefore, implantation of a second PHV within the first implanted device was the only available option.

The second CoreValve prosthesis was then deployed within the first PHV by the same technique. This was facilitated by the landmark of the first PHV, and the second PHV was successfully deployed slightly distal to the first. Aortogram after second PHV deployment revealed very trivial paravalvular leak (Fig. 6).

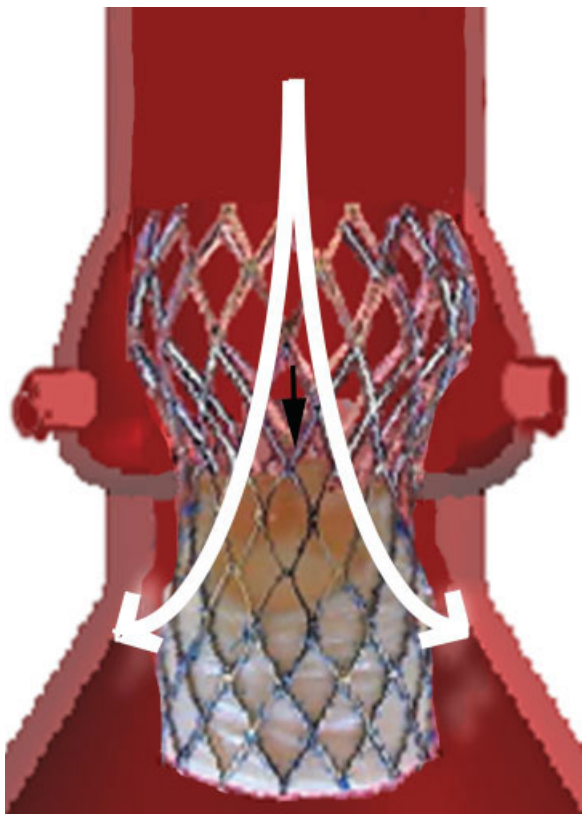

Fig. 5. Diagrammatic representation of the leak through the frame struts as a result of proximal deployment of the initial CoreValve prosthesis.

The patient was weaned off from the extracorporeal support system, the delivery system was removed, and the access sites were surgically repaired. The patient

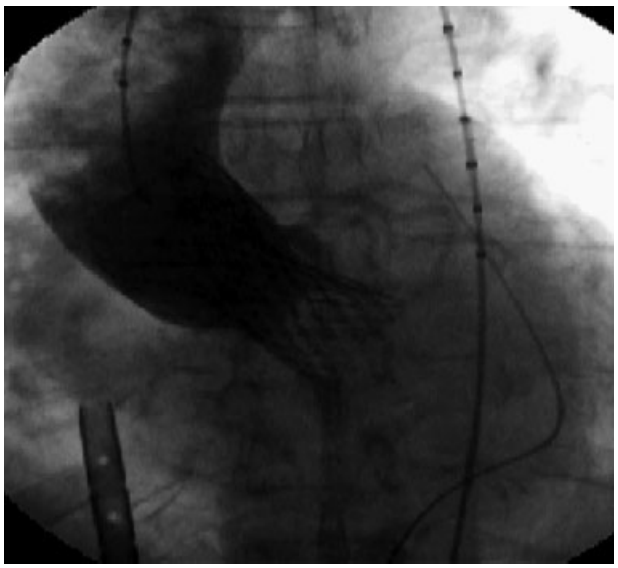

Fig. 6. Post second PHV deployment aortogram showing minimal contrast in the LV that cleared rapidly.

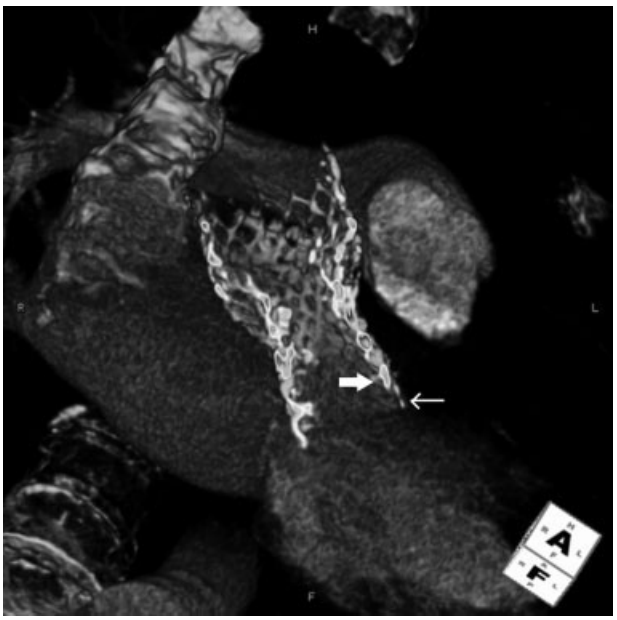

Fig. 7. CTA (saggital view) demonstrating CoreValve-in-CoreValve prostheses.

was then transferred to the coronary care unit where she was weaned off inotropic support and mechanical ventilation in the following 72 h.

RESULTS

Periprocedural

Immediately post–deployment, the MPG across the double prostheses was 8 mmHg. There was however, a new mild to moderate MR noted by transesophageal echocardiography (TEE) due to impingement of the anterior mitral valve leaflet by the misplaced first PHV. A supra-aortic angiogram documented patency of both coronary ostia. The entire procedure time was in excess of 300 min.

TEE performed several hours later revealed a completely excluded native aortic valve, a completely expanded CoreValve, circular frame geometry, proper function and stable hemodynamics of the second CoreValve prosthesis.

Clinically, the patient's CHF symptoms resolved with improvement of her NYHA functional class from IV to II.

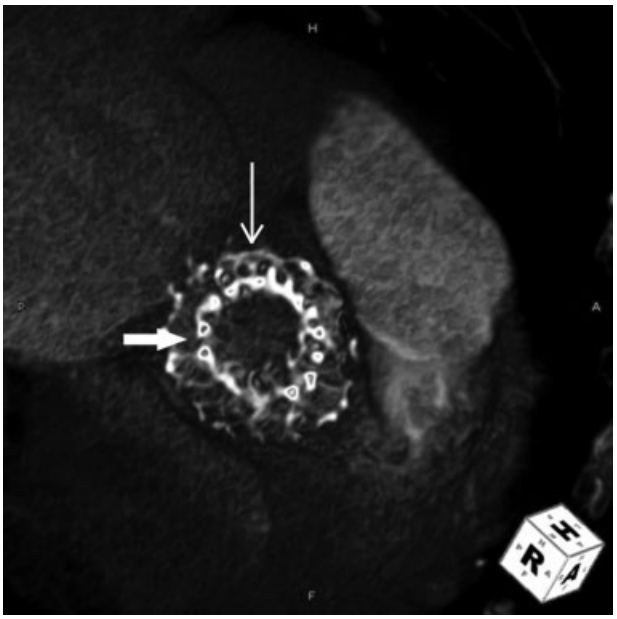

Fig. 8. CTA (axial view) demonstrating CoreValve-in-CoreValve prostheses.

Long Term

The patient has been followed up regularly and imaging studies were performed at 3 months, 6 months, 1 year, 2 years, and 3 years. The patient's clinical condition has been satisfactory over the past 3 years without further hospitalizations for CHF, and with maintenance of her NYHA functional class II status.

Echocardiography performed 3-years post-deployment showed a LVEF of 40%, a normal functioning CoreValve-in-CoreValve prostheses with a transvalvular gradient of 10 mmHg. There was no aortic regurgitation or paravalvular leaks noted. There was moderate MR and moderate MS with a calculated mitral valve orifice area of 1.4 cm^2 and MPG of 5.6 mmHg. Cardiac computed tomography showed stable valve-in-valve prostheses with no migration (Figs. 7–9).

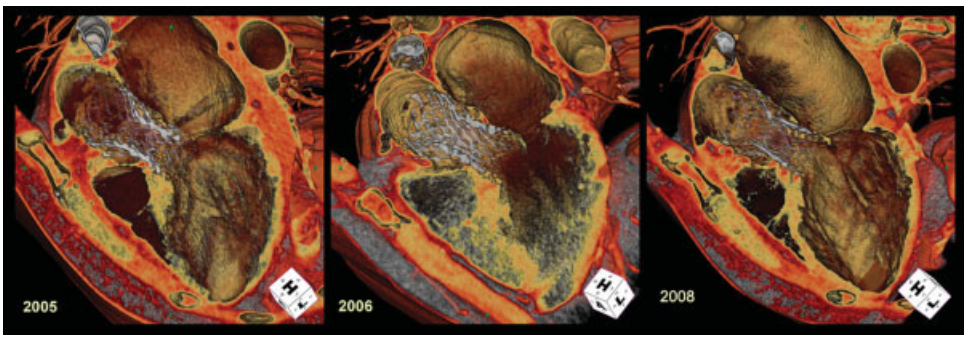

Fig. 9. Color CTA images demonstrating stability of the CoreValve prostheses over 3 years.

DISCUSSION

This patient has today the longest follow-up for the CoreValve prosthesis. Early results from both the CoreValve and Edwards-Sapien PHVs have been encouraging [2–4]. The devices have undergone rapid improvements, increasing the safety of implantation and reducing the risk of complications. However, the longer term durability of the PHVs is unknown. In this case, the CoreValve prosthesis demonstrated normal function without any structural deterioration or migration up to 3 years. Satisfactory hemodynamics was also maintained. This is the longest follow-up data available for the CoreValve prosthesis and is likely also to be one of the longest follow-up for any of the aortic PHVs.

Although the concept of using a CoreValve prosthesis to treat a degenerated surgical bioprosthesis has been demonstrated [5], the possibility of implanting a PHV-in-PHV was thus far unreported in the literature. This first ever case of a PHV-in-PHV implantation demonstrated concept feasibility, and has several important implications. This showed that a second CoreValve prosthesis could be implanted immediately over a first CoreValve prosthesis if the first device was released in a suboptimal anatomical location. Furthermore, implanting a CoreValve-in-CoreValve did not negatively affect either the immediate or longer term valve function or valve hemodynamics, and importantly, did not obstruct coronary blood flow. This also indicates that if and when the implanted CoreValve tissue valve degenerates over time, as do all tissue valves, the implantation of an additional CoreValve self expanding device inside the failing one is a feasible way of treating such patients.

Current experience with both the balloon expandable and self expandable PHVs have been in the treatment of severe symptomatic AS in high risk patients [2–4]. The use of a PHV to treat severe AR or predominant AR has to date been only a theoretical possibility. This case illustrates the feasibility of using the CoreValve prosthesis in patients with mixed aortic valve disease where the AR was the predominant lesion. It is thus possible that the CoreValve prosthesis could be used for patients with pure AR in the near future.

From this study it can be seen that accurate implantation of the PHV is of the utmost importance. Because of minimal calcification, accurate implantation was more difficult in this case and ICE did not provide optimal imaging. Slight misplacement resulted in severe AR which was corrected with a second device. However, the MR resulting from the PHV being released too far into the LVOT could not be reversed. The new mild to moderate MR post-deployment was likely caused by anterior mitral leaflet impingement. The MR initially improved to mild grade over 2 years but worsened again over the past year. This may be due to progression of the patient's rheumatic heart disease as evidenced by the decrease in MVA, although damage to the mitral valve from the misplaced prosthesis cannot be definitely excluded. The iatrogenic moderate MR however, has not affected the patient's functional status or LV function but close monitoring will be required.

With demonstration of the 3-year durability of the CoreValve and also feasibility and durability of the technique of implanting a PHV-in-PHV, the practice of AVR will be substantially altered. This case certainly generates more discussion on the current indications for choosing types of prostheses in surgical AVR. Perhaps bioprosthetic valves should become the prosthesis of choice in surgical AVR even in younger patients since there is a feasible percutaneous method to treat a degenerated bioprosthesis, avoiding the increased surgical risk of re-operation. Furthermore, as the delivery profile has been reduced from the 25F device used in this study to an 18F device used currently, the safety of aortic PHV implantation has improved. The percutaneous approach will likely become a viable option in the near future not just for the elderly patients that are now enrolled in registries and trials but also for a

younger population with the knowledge that the PHV can be re-implanted if degeneration occurs.

CONCLUSION

The CoreValve PHV has shown longer term durability up to 3 years, with no structural deterioration or migration and with maintenance of proper valve function. Treating mixed aortic valve disease with predominant AR has also been shown to be feasible. In addition, the feasibility as well as durability of a first ever PHV-in-PHV concept has been demonstrated. These can conceivably revolutionize the treatment of aortic valve disease and a new paradigm of thinking may be required.

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