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Case Reports

Percutaneous Re-Revalvulation of the Tricuspid Valve

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We report a successful percutaneous revalvulation of a dysfunctional tricuspid bioprothesis in an 8-year-old child. Five years after implanting a 25-mm Carpentier-Edwards valve in the tricuspid position, the prosthesis showed significant dysfunction with clinical right heart failure. A 26-mm Edwards-Sapien XT inverted aortic valve was successfully implanted through a 19F sheath using a jugular approach. Such procedure can significantly postpone the need for surgical replacement of a biological valve.

Key words: percutaneous valve; tricuspid valve; biologic valve prosthesis; off-label use

INTRODUCTION

Biological valves have a limited life-span. Till now, redo surgery was the only option to relieve dysfunction. We report on a new percutaneous technique to re-revalvulate a dysfunctional bioprothesis in tricuspid position (off-label indication with off-label in-patient loading).

CASE REPORT

An 8-year-old girl presented with progressive tricuspid valve prosthesis dysfunction 5 years after implantation. During infancy, multiple ventricular septal defects were closed at two separate occasions, including peroperative deployment of an Amplatzer cribriform device (AGA Medical corporation, Plymouth, MN) to occlude the apically located defects. All VSDs were closed, but the right ventricular Amplatzer disk did transect chordae of the tricuspid valve, causing a flail valve leaflet beyond repair within weeks. Consequently, a 25-mm Carpentier-Edwards pericardial valve system (Edwards, Irvine, CA) was implanted at the age of 3 years, together with an epicardial pacemaker. Five years later, she developed edema and signs of low output due to tricuspid valve dysfunction (mean gradient 12 mm Hg, regurgitation $^{3}/_{4}$) requiring repeat revalvulation. The option of percutaneous revalvulation was discussed with the parents; informed consent was obtained in accordance with local ethical guidelines.

Bench Testing

We performed an ex-vivo experiment for valve mounting and deployment, as the intended procedure included off-label use for the recipient and the implanted valve, as well as an off-label adapted technique for valve mounting and delivery (inverted valve).

- At the time of the procedure (May 2010), only the Sapien system (Edwards, Irvine, CA) had a valve sufficiently large for the implanted annulus. To deliver a sufficiently large stent in the 25-mm "soft" annulus, we chose the 26-mm Sapien XT valve. As the patient was a small 25-kg child, we explored the possibility to use the smallest available delivery system, at that time the 19F Novaflex. This system involves mounting and crimping the valve on the shaft more proximal of the balloon; only after insertion into the patient, the balloon is pulled into the valve; this maneuver allows the insertion sheath to be decreased to 19F (as opposed to 24F with the former Sapien Retroflex III system where the valve is crimped on the balloon). When implanting an aortic

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valve retrograde through the aorta, the valve is pulled over the balloon with the leaflets "downstream"; in the anticipated procedure, the valve is mounted "inverted", and the leaflets are pulled "upstream" over the balloon, which theoretically might tear the leaflets. We therefore confirmed the integrity of the valve leaflets after three "inverted" bench deliveries.

- A 25-mm Carpentier-Edwards pericardial valve has an inner diameter of 25 mm; the wall consists of a thin cuff followed by a stiff metallic ring. The 26-mm Edwards-Sapien XT valve has at full expansion an outer diameter of 26 mm when deployed with the delivered 25-mm balloon; the distal third is uncovered (aortic design to allow for coronary flow). Bench testing demonstrated adequate retention of the Sapien valve within the Carpentier valve if the stent of the Sapien valve was stradling the ring of the Carpentier valve (Fig. 1A and B).
- The Sapien valve is developed to open and close at high left ventricular-aortic pressures. The valve has recently been introduced in pulmonary position, where it operates at much lower pressures [1]. With the proximal stent fixed at 24 mm and the distal end at 26 mm, the Sapien valve opened and closed adequately in a water bath with minimal water gradients.

Procedure

The procedure was performed under general anesthesia. We preferred a jugular as opposed to a femoral approach as the Carpentier annulus was slightly cranially orientated, making progression of the delivery system easier. This approach would also give a more stable and aligned position of the Sapien XT valve within the Carpentier-Edwards valve during deployment.

- A very stiff 0.035″ guiding E-wire (Jotec, Hechingen, Germany) was positioned as distal as possible in the right pulmonary artery.
- A 19F sheath was inserted into the jugular vein and advanced into the right atrium.
- A delivery system with mounted Sapien valve was advanced until the valve was well within the jugular vein; the sheath was pulled proximal to the valve; the balloon was then retracted into the valve having a straight course of the delivery system at the right atrium-jugular vein level.
- The X-ray scope was rotated mildly in right-anterior oblique to get the Carpentier-Edwards valve ring perfectly perpendicular to the X beam (Fig. 2A).
- The valve was advanced into the Carpentier-Edwards valve, with the proximal edge of the valved stent being just proximal of the Carpentier-Edwards valve; the balloon was inflated until a predetermined volume during rapid ventricular pacing 240/min (Fig. 2A–C).

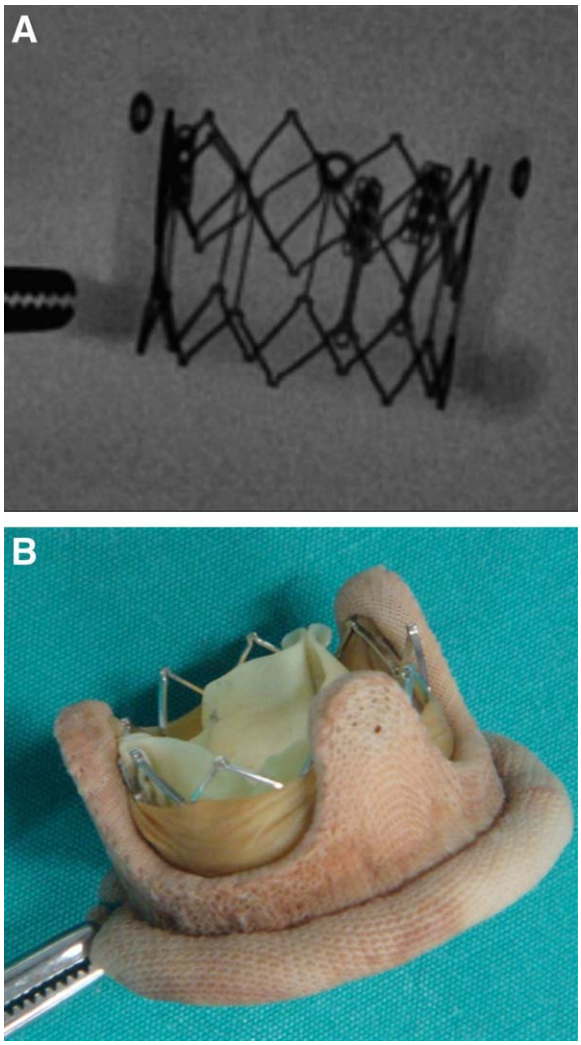

Fig. 1. A and B: Bench testing of deployment of a 26-mm Edwards-Sapien XT valve into a 25-mm Carpentier-Edwards valve; A: transluminated view and B: classic view. The Sapien stent has to straddle the Carpentier ring to get adequate retention, and because the distal third of the Sapien is uncovered (aortic design). The original Carpentier leaflets are spread open by the Sapien stent. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

- The balloon was then deflated, a stable position of the valved stent was confirmed at fluoroscopy, and the delivery system and guiding wire were removed.

Hemodynamic evaluation after valve deployment showed no residual gradient across the valve. Echocardiographic evaluation demonstrated laminar diastolic flow without gradient, and a mild regurgitation grade 1/4. Clinical signs of right heart failure disappeared within hours. The patient was discharged on low dose acetylsalicylic acid 1 mg/kg/day. Clinical and echocardiographic evaluation at 1 and 3 months showed persistence of the result.

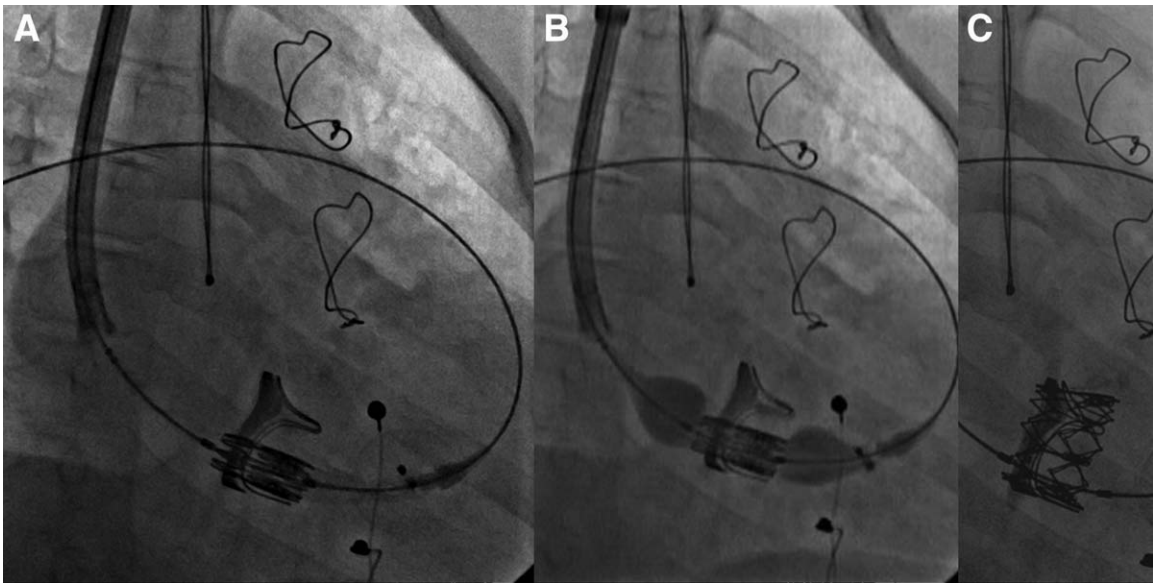

Fig. 2. A–C: Radioscopic frames from valved-stent deployment. A: Stiff 0.035" wire from right jugular vein into right pulmonary artery; mild right anterior oblique to get the Carpentier-Edwards valve ring perfectly perpendicular to the X beam; Edwards-Sapien XT ready for deployment with the proximal edge of the stent immediately proximal to the Carpentier-Edwards valve. B: the Sapien valve is slowly deployed during rapid ventricular pacing. C: the valved stent is fully deployed with tight fit at the Carpentier ring, and some flaring more distally.

DISCUSSION

The use of a biological valve prosthesis has always been appealing as there is no need for full anticoagulation. Major drawbacks are lack of growth in children, and the limited functionality of the valve over time. The 5 year freedom rate for reintervention of the Carpentier-Edward valve has been estimated to be 85% in aortic position, 75% in mitral position, 97% and 92% in tricuspid and pulmonary position, respectively [2–5]. When dysfunction becomes clinically significant, the only option has been to replace the valve surgically, however with associated morbidity and mortality.

With the advent of large transcatheter valves, the option has been created to prolong the life-span of such biological valve. The procedure for tricuspid position as described in this patient was straightforward and successful. Although we cannot predict the duration of proper valve functioning in tricuspid position, it seems reasonable to extrapolate data from surgically inserted valves, as the leaflets are prepared similarly. One might even anticipate that a second percutaneous valve may be inserted in this patient in due time, unless exaggerated growth would preclude such procedure due to size-mismatch.

The transcatheter valve in tricuspid position opened well, but showed mild regurgitation. Careful echocardiographic examination did not reveal an abnormal valve motion. These valves are known to close nearly complete when positioned in aortic position. Possible causes of regurgitation are either insufficient coaptation at lower right ventricular pressures or mild leaflet damage due to "inverted loading." Additional investigation is therefore warranted.

Burst pacing was used in this procedure to enhance the safety by obtaining a very stable position across the Carpentier-Edwards valve during deployment; however, it is unclear if this delivery system is "unstable" during deployment in the low-pressure right heart system. We would not use pacing when deploying this valve in the pulmonary position.

In our patient, we opted for a transjugular approach, thereby obtaining a better angle when positioning the stent, and a more stable aligned position during balloon inflation. The inverted loading of the valve onto the balloon (off-label maneuver) did not appear to have damaged the valve in the bench tests nor in this clinical case. This however needs to be better evaluated. We anticipate that if required such valved stent can be delivered in the mitral or tricuspid position, with an anterograde or retrograde approach by either transatrial (femoral or jugular access) or transventricular (apical access) route.

This case illustrates that a valved stent can be deployed virtually "anywhere" in the heart, provided that a stiff ring is available to anchor the valved stent. A suitable stiff region could be a shrunken graft or conduit in pulmonary position, a calcified aortic ring in the elderly patient, or a prosthetic ring in tricuspid or mitral valve position with a prosthesis or an incomplete ring.

CONCLUSIONS

In well selected patients, transcatheter re-revalvulation appears to be a safe and effective procedure. This technique will allow to postpone replacement-surgery for many years, which makes the use of biologic valves much more attractive.

REFERENCES

1. Boone RH, Webb JG, Horlick E, Benson L, Cao QL, Nadeem N, Kiess M, Hijazi ZM. Transcatheter pulmonary valve implantation using the Edwards SAPIEN transcatheter heart valve. Catheter Cardiovasc Interv 2010;75:286–294.
2. Aortic Aupart MR. Perimount pericardial bioprosthesis for aortic calcified stenosis: 18 Year experience with 1.133 patients. J Heart Valve Dis 2006;15:768–776.
3. Pomar JL, Jamieson WR, Pelletier LC, Gerein AN, Brownlee LT. Mitroflow pericardial bioprosthesis: Clinical performance to 10 years. Ann Thorac Surg 1995:60:305–309.
4. Tricuspid Carrier M, Hébert Y, Pellerin M, Bouchard D, Perrault L, Cartier R, Basmajan A, Pagé P, Poirier N. Tricuspid valve replacement: An analysis of 25 years of experience at a single center. Ann Thorac Surg 2003;75:47–50.
5. Pulmonary Fiore AC, Rodefeld M, Turrentine M, Vijay P, Reynolds T, Standeven J, Hill K, Bost J, Carpenter D, Tobin C, Brown J. Pulmonary valve replacement: A comparison between 3 biological valves. Ann Thorac Surg 2008;85: 1712–1718.