

Transcatheter Tricuspid Valve-in-Valve Replacement

with an Edwards SAPIEN 3 Valve

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A few case reports and case series have documented the outcomes in patients with tricuspid bioprosthetic valvular degeneration who underwent transcatheter implantation of the Medtronic MELODY and the Edwards SAPIEN XT and SAPIEN 3 valves. In this report, we describe the case of a 49-year-old woman with severe bioprosthetic tricuspid valvular stenosis and multiple comorbidities who underwent transcatheter tricuspid valve replacement with a SAPIEN 3 valve. (*Tex Heart Inst J* 2017;44(3):209-13)

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Surgical valve replacement has been the mainstay of therapy for severe valvular stenosis and regurgitation. However, the decision regarding bioprosthetic versus mechanical valve replacement remains debatable when young patients are involved.¹ Bioprosthetic valves can lead to early degeneration and dysfunction and to the consequent need for reoperation because of the intrinsic properties of the valvular material.¹ Mechanical valves, as the alternative, carry higher risks of valvular thrombosis, of stroke, and of increased bleeding that can necessitate long-term anticoagulation.¹

The decision regarding definitive therapy for patients with bioprosthetic dysfunction remains difficult. Transcatheter bioprosthetic valve replacement has become an excellent alternative to repeat surgical valve replacement when comorbid conditions and prior sternotomies heighten patients' surgical risk. This can become even more appealing in cases of tricuspid bioprosthetic valve dysfunction. Investigators have shown higher mortality rates when reoperation is performed in the tricuspid position.² The Placement of Aortic Transcatheter Valves (PARTNER) trials have shown consistently favorable outcomes in high-surgical-risk and inoperable patients with severe native aortic stenosis undergoing transcatheter aortic valve implantation (TAVI) of an Edwards valve (SAPIEN first generation, SAPIEN XT, and SAPIEN 3; Edwards Lifesciences Corporation; Irvine, Calif).^{3,4} These investigators have also documented excellent durability, without bioprosthetic degeneration, at the 5-year follow-up evaluation.^{3,4} Valve-in-valve therapies have been reported in the tricuspid, pulmonic, mitral, and aortic positions, with varying results.⁵ A few case reports and case series have documented outcomes in patients with tricuspid bioprosthetic valvular degeneration who underwent transcatheter therapies with the MELODY[®] Transcatheter Pulmonary Valve (Medtronic, Inc.; Minneapolis, Minn) and the Edwards SAPIEN XT and SAPIEN 3 valves.⁶⁻⁹ We describe the case of a woman with severe bioprosthetic tricuspid valve (TV) stenosis who underwent transcatheter TV replacement with use of the Edwards SAPIEN 3 valve.

Case Report

In February 2015, a 49-year-old woman presented with symptoms of severe right-sided heart failure and with a history of prior polysubstance abuse and of end-stage renal disease necessitating hemodialysis. She also had chronic viral hepatitis C with suspected cirrhosis and had developed infective endocarditis, resulting in severe tricuspid regurgitation. In 2008, she had undergone surgical TV replacement with a 31-mm Carpentier-Edwards PERIMOUNT bioprosthesis (Edwards Lifesciences).

The patient had begun to experience signs and symptoms consistent with right-sided heart failure. She underwent multiple hospital admissions for fatigue, severe dyspnea, peripheral edema, anasarca, and recurrent ascites. The current physical examination revealed lethargy, an elevated jugular venous pressure with cannon A waves, a grade

3/6 diastolic murmur heard best at the left lower sternal border, diminished breath sounds at the bilateral bases, abdominal ascites, and pitting edema in the bilateral lower extremities. During her evaluation, transthoracic echocardiography revealed severe bioprosthetic TV stenosis (Fig. 1). Her mean transvalvular gradient was 14.5 mmHg; her peak transvalvular gradient, 23 mmHg; and her peak velocity, 2.42 m/s.

The heart team decided to proceed with off-label use of an Edwards SAPIEN 3 valve because of the patient's overall frailty and significant comorbid conditions: her estimated prohibitive surgical risks (Society of Thoracic Surgeons scores for mitral valve replacement) were 14% for death and 43% for morbidity or death.

After informed consent was obtained, the patient was brought to the cardiac catheterization laboratory in a fasting, nonsedated state. Both of her groins were prepared and draped in the usual sterile fashion. The patient received conscious sedation by means of systemic fentanyl and midazolam administration. With use of a 4F microintroducer kit (Vascular Solutions, Inc; Minneapolis, Minn), access to the right femoral vein was attained via the modified Seldinger technique to place an 11-cm, 7F sheath.

An additional left femoral vein puncture was performed via a micropuncture needle, and a 6F venous sheath was advanced without difficulty. A deflectable quadripolar catheter (St. Jude Medical, now part of Abbott Laboratories; St. Paul, Minn) was advanced into the rather large right atrium and into the ostium of the coronary sinus. A pacemaker tip was initially placed in the anterior intraventricular venous branch; however, because this particular patient's anatomy produced high torque while the leads were seated at the ostium of the coronary sinus, the leads were redeployed more distally into a middle cardiac vein location, and the tips of the leads were extended further into that vein to ensure optimal stability during sheath manipulation and valve deployment. The patient was then given heparin in order to achieve an activated clotting time of longer than 250 s.

Next, a 7F Swan-Ganz monitoring catheter (Cardinal Health; Dublin, Ohio) was advanced into the 7F sheath and across the tricuspid bioprosthesis, to the pulmonary capillary wedge position. Hemodynamic values were obtained upon insertion into the right atrial, right ventricular, pulmonary arterial, and pulmonary capillary wedge positions. The mean right atrial pressure was 28 mmHg, with an A wave of 33 mmHg. A 0.035-in Amplatz Extra-Stiff guidewire (Cook Medical Inc.; Bloomington, Ind) was then advanced into the Swan-Ganz catheter and parked in the distal right lower pulmonary artery for support. The Swan-Ganz catheter was then removed, and the 7F, 11-cm sheath was exchanged over the Amplatz wire for a 16F Edwards eSheath Introducer Set (Edwards Lifesciences) (Fig. 2).

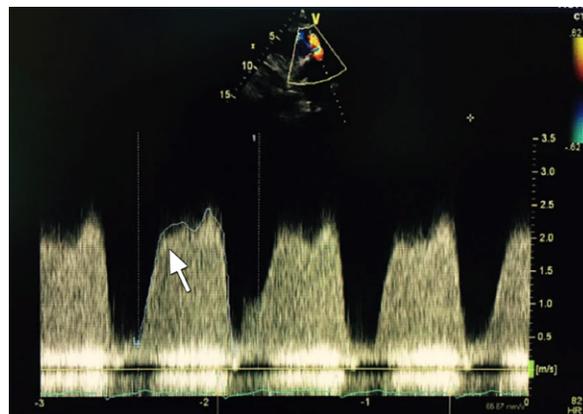


Fig. 1 Transthoracic echocardiogram with color-flow Doppler shows severe tricuspid stenosis with a mean transvalvular gradient of 14.5 mmHg and a peak velocity of 2.42 m/s. Arrow points to the transtricuspid gradient.

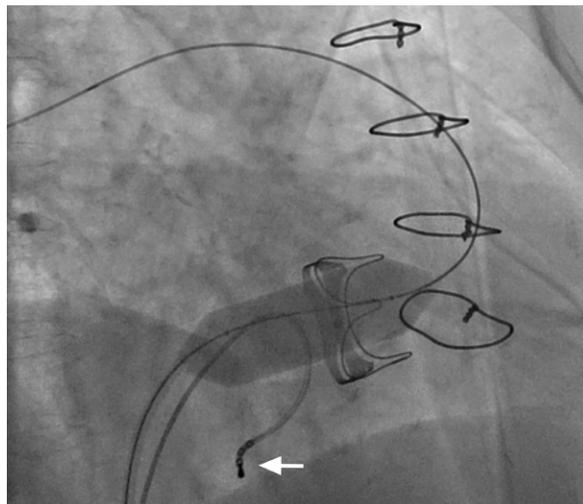


Fig. 2 Initial fluoroscopic image shows the 31-mm Carpentier-Edwards PERIMOUNT valve in the tricuspid position during balloon valvuloplasty and its relationship with the coronary sinus pacing leads (arrow).

Next, balloon valvuloplasty of the tricuspid bioprosthesis was performed, with and without rapid ventricular pacing, by means of a 20-mm \times 4.5-cm True Dilatation[®] Balloon Valvuloplasty Catheter (BARD Peripheral Vascular, Inc.; Tempe, Ariz) (Fig. 3). The valvuloplasty balloon was then removed. The 29-mm Edwards SAPIEN 3 transcatheter heart valve with the 29-mm Edwards Commander delivery system (Edwards Lifesciences) was inserted over the Amplatz wire in the inferior vena cava. Under fluoroscopic guidance, the valve was then advanced into the tricuspid bioprosthesis and positioned in the usual manner for SAPIEN 3 valve deployment, with use of the prior stent's frame as a reference. Under rapid ventricular pacing and precise positioning, the valve was deployed with

excellent results (Fig. 4). The delivery system and the Amplatz guidewire were subsequently removed. Post-deployment transthoracic echocardiograms confirmed a well-seated valve with optimal placement and no paravalvular regurgitation. Doppler measurements showed improvement of the transtricuspid gradient. The mean transvalvular gradient improved to 3 mmHg and the peak velocity to 1.5 m/s. Right-sided heart catheterization revealed immediate improvement in the patient's

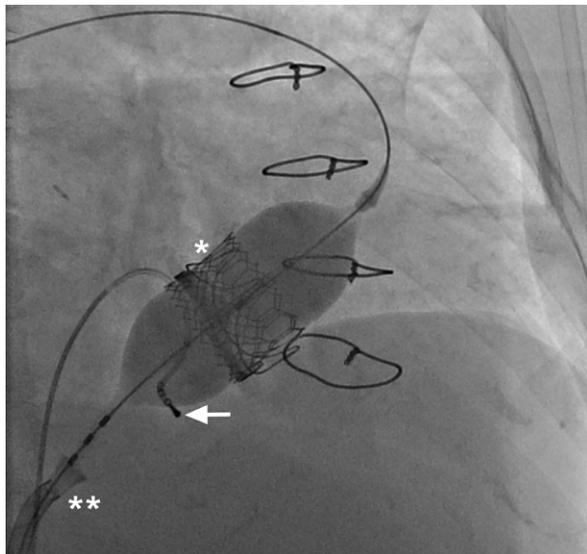


Fig. 3 Fluoroscopic image shows Edwards SAPIEN 3 valve deployment in relationship with the prosthetic valve struts. Arrow points to the coronary pacing wire; one asterisk is positioned at the valve-in-valve; 2 asterisks are positioned at the Edwards Commander delivery system.

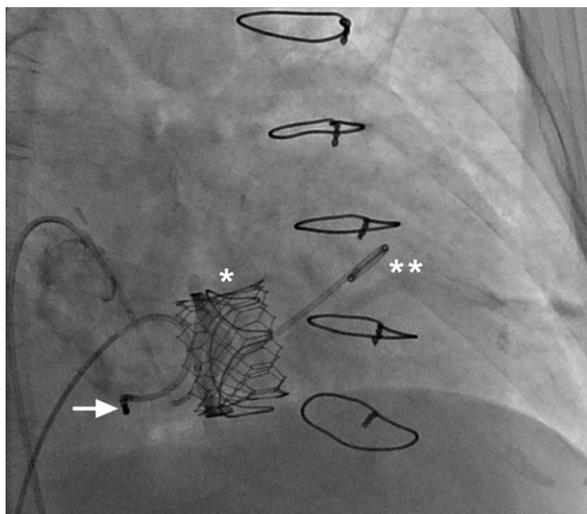


Fig. 4 Fluoroscopic image shows the Edwards SAPIEN 3 valve-in-valve after deployment, in relationship with the prosthetic valve struts. Arrow points to the coronary pacing wire; one asterisk is positioned at the valve-in-valve; 2 asterisks are positioned at the pigtail catheters.

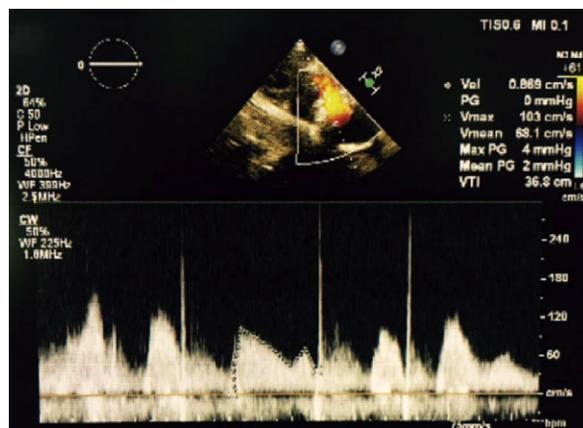


Fig. 5 Transthoracic echocardiogram with color-flow Doppler shows valve-in-valve bioprosthetic tricuspid function with a mean transvalvular gradient of 2 mmHg and a peak velocity of 0.69 m/s, suggesting substantial reduction in gradient severity after percutaneous transcatheter valve implantation.

intracardiac hemodynamic values. The mean right atrial pressure improved to 15 mmHg, with an A wave of 19 mmHg. Repeat echocardiographic evaluation of the valve-in-valve bioprosthetic tricuspid function showed a mean transvalvular gradient of 2 mmHg and a peak velocity of 0.69 m/s, suggesting a substantial reduction in gradient severity (Fig. 5).

The patient's venous sheaths were removed, and hemostasis was obtained via 2 figure-of-eight sutures. The patient tolerated the procedure well with no immediate periprocedural sequelae. She was transported to the intermediate care unit in stable condition. She reported immediate improvement in her dyspnea and fatigue. She was discharged from the hospital after an uneventful postoperative stay of 10 days and was seen as an outpatient 4 months later, when she underwent liver biopsy for hepatitis C-related cirrhosis.

Discussion

The concept of using TAVI in repair of degenerated bioprosthetic valves was first presented with a transfemoral CoreValve system (Medtronic) and then was adopted by Edwards.¹⁰⁻¹² Valve-in-valve has been an increasingly appealing strategy, but the data are few on percutaneous treatment of severe TV degeneration with the SAPIEN 3 device.⁹ Herein we describe a case of a patient with severe bioprosthetic TV stenosis who was successfully treated with transfemoral TAVI via the 29-mm Edwards SAPIEN 3 Commander system.

This case demonstrates the optimal performance of the SAPIEN 3 valve in this particular anatomy. We selected the SAPIEN 3 because of our extensive experience in percutaneous valve replacement with this device. The ability to steer a 16F eSheath and Commander delivery

system of relatively low profile seems particularly suitable for use on a transfemoral route in TV replacement.

Our patient had a 31-mm Carpentier-Edwards PERIMOUNT bioprosthesis. The industry-reported internal diameter of the stent is 31 mm, but the true internal diameter is closer to 28.5 to 30 mm because of the pericardial tissue sewn inside the stent frame. The effective internal prosthetic area is, therefore, approximately 638 to 707 mm². The 29-mm Edwards SAPIEN 3 valve, with a height of 22.5 mm and a larger coverage area of up to 683 mm², was the optimal choice in this patient. The development of the polyethylene terephthalate outer skirt on the proximal base of this valve has the added benefit of reducing paravalvular regurgitation after deployment. Transjugular, transatrial, and transfemoral vascular access for this procedure have been described.^{13,14} We chose transfemoral access because a small-bore 16F sheath used with the 29-mm Edwards SAPIEN 3 proved to be well suited to the anatomic challenge of routing this valve into the tricuspid position.

Last, we performed balloon valvuloplasty with rapid ventricular pacing from the middle cardiac vein. Conventional aortic valve deployments are performed while on a rapid ventricular pacing sequence through a transvenous catheter—across the tricuspid annulus, in close contact with the right ventricular septum. Percutaneous TV deployment is particularly challenging because transvenous pacemakers are customarily deployed across the TV into the right ventricular septum. However, given that valve deployment in this instance was essentially in the TV position, the aim of the temporary wire placement in the middle cardiac vein was to enable rapid RV pacing with minimal chance of dislodging pacing leads during manipulation of the SAPIEN 3 delivery system. To this end, a deflectable quadripolar catheter in the middle cardiac vein location provided reliable ventricular pacing without engaging the tricuspid annulus. Pacing from the left ventricle would have obliged unnecessary aortic-valve-crossing maneuvers. Rapid ventricular pacing was ultimately performed and was shown to provide stabilization and to improve deployment accuracy in this consciously sedated patient who had substantially elevated right atrial pressures.

Transfemoral access and coronary sinus pacing might provide considerable procedural improvement when compared with a prior reported case⁸ of successful transjugular deployment of an earlier-generation device without rapid pacing. The technique described by Mortazavi and colleagues,⁸ although successful, might have required surgical hemostasis after the device was retracted. Further, deployment in the absence of ventricular pacing can be challenging. A transfemoral approach and a pacing sequence on deployment have made this case similar to that of a conventional transcatheter valve implantation and therefore easier to plan and execute.

Particular care was used during the procedure while manipulating catheters, the delivery system, and the support wire, because the SAPIEN 3 valve and delivery system was originally designed to navigate a more resistant structure (the aorta) and to deploy in the aortic annulus. The Amplatz Extra-Stiff wire provided exceptional support while we navigated the inferior vena cava, and the steering ability of the Commander system minimized trauma to the right atrium and ventricle. Close clinical follow-up, a full surgical team, and extracorporeal membrane oxygenation on standby—with echocardiography both intraoperatively and during early postoperative recovery—have been used to diagnose and treat atrial perforations sooner rather than later.

In conclusion, the SAPIEN 3 Commander System seems to be suitable for valve-in-valve transcatheter TV replacement because of its low-profile, technically easy deployment. Although ours was an off-label use of this device, it might provide a valid, minimally invasive alternative in poor surgical candidates or in patients in whom comorbidities pose substantial risk. Careful radiologic, angiographic, and anatomic planning remain the mainstays for procedural success as transcatheter valve replacement continues to progress in its application to extreme situations.

References

1. Chikwe J, Chiang YP, Egorova NN, Itagaki S, Adams DH. Survival and outcomes following bioprosthetic vs mechanical mitral valve replacement in patients aged 50 to 69 years. *JAMA* 2015;313(14):1435-42.
2. Jones JM, O'Kane H, Gladstone DJ, Sarsam MA, Campalani G, MacGowan SW, et al. Repeat heart valve surgery: risk factors for operative mortality. *J Thorac Cardiovasc Surg* 2001; 122(5):913-8.
3. Mack MJ, Leon MB, Smith CR, Miller DC, Moses JW, Tuzcu EM, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet* 2015;385(9986):2477-84.
4. Kapadia SR, Leon MB, Makkar RR, Tuzcu EM, Svensson LG, Kodali S, et al. 5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet* 2015;385(9986):2485-91.
5. Webb JG, Wood DA, Ye J, Gurvitch R, Masson JB, Rodes-Cabau J, et al. Transcatheter valve-in-valve implantation for failed bioprosthetic heart valves. *Circulation* 2010;121(16): 1848-57.
6. Mick SL, Kapadia S, Tuzcu M, Svensson LG. Transcatheter valve-in-valve tricuspid valve replacement via internal jugular and femoral approaches. *J Thorac Cardiovasc Surg* 2014;147 (5):e64-5.
7. Filsoof DM, Snipelisky DF, Shapiro BP. Use of a Melody pulmonary valve in transcatheter valve-in-valve replacement for tricuspid valve bioprosthesis degeneration. *Tex Heart Inst J* 2014;41(5):511-3.
8. Mortazavi A, Reul RM, Cannizzaro L, Dougherty KG. Transvenous transcatheter valve-in-valve implantation after

- bioprosthetic tricuspid valve failure. *Tex Heart Inst J* 2014;41(5):507-10.
9. Schaefer A, Conradi L, Seiffert M, Lubos E, Blankenberg S, Reichenspurner H, et al. Valve-in-valve procedures in failing biological xenografts using a novel balloon-expandable device: experience in aortic, mitral, and tricuspid positions. *Thorac Cardiovasc Surg* 2016;64(5):366-73.
 10. Wenaweser P, Buellfeld L, Gerckens U, Grube E. Percutaneous aortic valve replacement for severe aortic regurgitation in degenerated bioprosthesis: the first valve in valve procedure using the CoreValve Revalving system. *Catheter Cardiovasc Interv* 2007;70(5):760-4.
 11. Ye J, Cheung A, Lichtenstein SV, Pasupati S, Carere RG, Thompson CR, et al. Six-month outcome of transapical transcatheter aortic valve implantation in the initial seven patients. *Eur J Cardiothorac Surg* 2007;31(1):16-21.
 12. Walther T, Kempfert J, Borger MA, Fassl J, Falk V, Blumenstein J, et al. Human minimally invasive off-pump valve-in-a-valve implantation. *Ann Thorac Surg* 2008;85(3):1072-3.
 13. Kasel AM, Cassese S, Bleiziffer S, Amaki M, Hahn RT, Kasrati A, Sengupta PP. Standardized imaging for aortic annular sizing: implications for transcatheter valve selection. *JACC Cardiovasc Imaging* 2013;6(2):249-62.
 14. Raval J, Nagaraja V, Eslick GD, Denniss AR. Transcatheter valve-in-valve implantation: a systematic review of literature. *Heart Lung Circ* 2014;23(11):1020-8.