Unsuccessful Transfemoral Tricuspid Valve-in-Ring Implantation: Case Report and Literature Review

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ABSTRACT
Transcatheter tricuspid valve-in-ring implantation has emerged as a potential alternative to surgery for high-risk patients with symptomatic severe tricuspid regurgitation. However, the rigidity, open shape, and open configuration of the ring may lead to imperfect positioning, resulting in severe paravalvular leak. Particular attention should be paid to sizing and wire position with respect to the ring while implanting the valve.

Case Report
A 75-year-old woman was repeatedly admitted for right heart failure in the context of recurrent severe tricuspid regurgitation 2 years after a surgical aortic valve replacement (Edwards Magna Ease 21; Edwards Lifesciences, Irvine, CA) for severe aortic stenosis and tricuspid annuloplasty with a 26-mm Carpentier-Edwards ring (Edwards Lifesciences). Transthoracic echocardiography showed a moderately dilated right ventricle with preserved function. The left ventricle ejection fraction was 65%, the mean invasive pulmonary pressure was 25 mm Hg, and the transprosthetic aortic gradient was 11 mm Hg. Considering the patient’s history of breast radiotherapy, a difficult recovery from her previous surgery, and the calculated risk scores (Society of Thoracic Surgeons Predicted Risk of Mortality [STSPROM], 9.6%; European System for Cardiac Operative Risk Evaluation [EUROSCORE] II, 8.34%), the heart team decision was an off-label use of an Edwards SAPIEN 3 (Edwards Lifesciences) transcatheter heart valve (THV) for transfemoral valve-in-ring implantation.

Ethics Statement: The research reported has adhered to the Helsinki ethical principles for medical research involving human beings.

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After insertion of a pacing catheter into the coronary sinus via a jugular vein, the procedure was performed under general anesthesia with transoesophageal echocardiographic guidance in the cardiac catheterization laboratory. A 6F multipurpose diagnostic catheter was used to cross the tricuspid valve, and an Amplatzer Superstiff ST1 wire (Boston Scientific, St Paul, MN) was inserted through the diagnostic catheter into the right pulmonary artery. By using the computed tomography (CT) scan measurement (Fig. 1, A and B) under rapid pacing at 180 beats/min, a 23-mm Edwards balloon was inflated in the ring to assess the movement of the balloon and wire (Fig. 1, C and D; Video 1, view video online). Because the wire seemed well centered in the ring and the balloon was of adequate size, a 26-mm Edwards SAPIEN 3 (−1 mL) THV mounted on a transfemoral Edwards Commander Delivery System in an antegrade position was deployed under rapid pacing (Fig. 1, E and F; Video 2, view video online). Postimplantation, tricuspid regurgitation remained severe, but from a different location. Because of the rigidity, oval shape, and open configuration of the ring, the valve was imperfectly positioned with severe regurgitation between the THV and the annulus (Fig. 1G–I). Complete atrioventricular (AV) block occurred immediately after deployment.

After multidisciplinary discussion, a surgical valve replacement was performed on day 4 (aortic clamping: 45 minutes, extracorporeal circulation: 2 hours). During the open heart surgery, the THV was found to be solidly anchored by the 2 extremities of the open tricuspid ring (Fig. 1J), grasping the misplaced THV device like 2 fingers.

Recovery was slow: 60 days in the intensive care unit due to difficulty in weaning the patient from mechanical ventilation due to severe tricuspid regurgitation.

**Novel Teaching Points**

- Transcatheter TVIR implantation using the Edwards balloon-expandable valve has emerged as a potential alternative to surgery for high-risk patients with recurrent symptomatic severe tricuspid regurgitation after surgical ring repair.
- The rigidity, open shape, and open configuration of the ring may lead to imperfect positioning, resulting in severe PVL.
- Particular attention should be paid to sizing and wire position with respect to the ring while implanting the valve.

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**Figure 1.** (A, B) The size of the transcatheter heart valve (THV) was selected using the ring size as a reference and the computed tomography (CT) measurement (diameters: 17.5 × 25.9 mm, area: 3.618 cm², perimeter: 69.5 mm, derived diameter: 23.4 mm). (C) Fluoroscopy showing the pacemaker lead (arrow) in the coronary sinus via a jugular vein, the tricuspid ring, the aortic bioprosthesis (Ao), and a 6F multipurpose diagnostic catheter via the femoral vein to the right pulmonary artery. **Asterisk** showing the extremities of the tricuspid ring. (D) A 23-mm Edwards balloon inflated in the ring to assess the movements of the balloon and wire. The pacemaker lead moved backwards (arrow position in C and D). (E) A 26-mm Edwards SAPIEN 3 THV (−1 mL) (Edwards Lifesciences, Irvine, CA) mounted on a transfemoral Edwards Commander Delivery System in an antegrade position. **Asterisk** showing the extremities of the tricuspid ring. (F) Valve deployment under rapid pacing. (G) En face fluoroscopic view showing the relationship among the SAPIEN 3 THV, tricuspid ring, and aortic bioprosthesis. **Asterisk** showing the extremities of the tricuspid ring. (H) CT scan reconstruction showing the relationship among the SAPIEN 3 THV, tricuspid ring, and aortic bioprosthesis, as well as the relationship of the pacemaker lead to the ring and THV. CT scan showed that it passed by the side of the THV. **Asterisk** showing the extremities of the tricuspid ring. (I) Drawing explaining the distortion mechanism that might have led to an eccentric ejection force that resulted in THV malpositioning. (J) Picture from the surgical intervention showing the SAPIEN 3 THV entrapped by the 2 extremities of the tricuspid ring. **Asterisk** showing the extremities of the tricuspid ring.
| Age and sex | Ring | Valve approach | Pacing | Wire | Predilatation | PVL | Postintervention gradient |
|-------------|------|----------------|--------|------|---------------|-----|--------------------------|
| Mazzitelli et al. | 61 y, female | Carpentier Edwards (CE) (Edwards Lifesciences, Irvine, CA) 26 | XT 26 Transatrial (a) | LV apex | RV apex | No | Mild | 4 mm Hg |
| Cabasa et al. | 68 y, female | CE 32 | XT 29 +1 cc Transfemoral | NA | PA | No | Mild | 3 mm Hg |
| Condado et al. | 21 yr, female | CE 26 | Melody 22 mm (Medtronic) Transfemoral | No | RV apex | Yes | PVL | Severe → Mild (c) | 4 mm Hg |
| Piliero et al. | 62 y, female | CE 32 | XT 29 mm Transfemoral | LV apex | PA | No | Mild | 5 mm Hg |
| Girdauskas et al. | 57 y, female | CE 32 | XT 29 mm +2 cc Transapical | Epicardial SVC | No | Trace | 3 mm Hg |
| Bouleti et al. | 44 y, male | CE 30 | XT 26 Transfemoral | Pacing | RV apex | No | Mild | 3-5 mm Hg |
| | 69 y, male | CE 30 | XT 26 Transfemoral | Pacing | RV apex | No | None | 3-5 mm Hg |
| | 58 y, female | CE 32 | XT 26 Transfemoral | Pacing | RV apex | No | Moderate to severe | 3-5 mm Hg |
| Reichart et al. | 77 y, female | 34 contour 3-dimensional ring Medtronic (Minneapolis, MN) | SAPIEN 3 (Edwards Lifesciences) 29 +2 cc Transfemoral (b) | Pacing | RV apex | No | Mild | NA |
| Noble et al. | 75 y, female | CE 26 | SAPIEN 3 26 -1 cc Transfemoral | Coronary sinus PA | Yes | Severe | NA |
| Aboulhosn et al. | 5-69 y, (d, e) | 50% CE (f) | 85% Edwards 15% Melody | 56% | NA | 50% | PVL in 75% (g) | 0-5 mm Hg (h) |

Combined procedure: (a) mitral and tricuspid procedure; (b) TAVI and tricuspid procedure; (c) PVL of 17 × 10 mm treated by a vascular plug 4; (d) 22 patients, but 20 had TVIR. Percentages are presented for 20 patients. The 2 patients without valve implantation had a balloon sizing that showed no appreciable landing zone or persistent tricuspid regurgitation through the open portion of the annuloplasty ring; (e) 45% of congenital disease; (f) all rings were open except 1 (size 30-32 for half of the cases); (g) most were mild or trivial PVL. During the index procedure or during follow-up, 6 patients had moderate or severe PVL that was treated with vascular plugs, another TVIR, or surgical valve replacement; (h) median mean gradient was 4 mm Hg.

NA, not available; PA, pulmonary artery; PVL, paravalvular leak; RV, right ventricle; SVC, superior vena cava.
ventilation and the need for tracheostomy, complicated by polyneuropathy of the critically ill and terminal kidney failure. The patient remained hospitalized for more than 1 year. She was discharged with dialysis 3 times per week.

Discussion

The worldwide experience in TVIR remains limited. The first case of TVIR was reported by the German Heart Center in Munich in 2013, performed by off-pump transatrial approach via an anterolateral minithoracotomy and combined with a mitral valve-in-ring. Several successful case reports were subsequently published and are described in Table 1. The largest series to-date is the report from an international registry including 22 patients with the intent to perform TVIR implantation, with 20 finally treated. Different ring types were involved, the Carpentier-Edwards Classic, as in our case, being the most common (50%). Valves used were the Edwards SAPIEN (85%) and Medtronic Melody (15%) (Medtronic Inc., Minneapolis, MN). Procedural complications were 1 valve embolization (recaptured and a second valve implanted by a hybrid approach) and 1 valve malpositioning requiring a second valve to treat severe paravalvular leak (PVL). As in our case, severe PVL, most often in the open medial aspect of the ring, was the most common complication (20%) treated by a second valve implantation (n = 1) and occluder device implantation (3). Functional capacity was improved in 70% of this cohort.

Transcatheter implantation of vascular plugs was not attempted in our case considering the gap between the ring and the THV, which seemed too large to be efficiently closed, as well as the potential risk of THV embolization during plug deployment. This latter fear was unfounded because the THV was solidly anchored by the 2 extremities of the ring (Fig. 1J).

The sizing process is a challenging issue in all valve-in-valve and valve-in-ring procedures. Tricuspid rings are not optimal for later valve-in-ring implantation: The most frequently used devices are the rigid Carpentier-Edwards rings, which are incomplete rings with an oblong C shape, open on the septal annulus to avoid placing sutures close to the AV node, and nonplanar to accommodate the shape of the tricuspid annulus as it curves toward the aortic root. Because our patient had a rigid aortic bioprosthesis valve, no distortion of the aortic root ensued. This may not have been the case with a native aortic valve. Another scenario might be a wire misalignment that directed the THV device outside the tricuspid ring during the implantation procedure. An en face view would have been useful to better appreciate the relationship between the ring and the wire position before the valve deployment.

With respect to technical aspects, we opted for a wire positioning in the right pulmonary artery rather than in the right ventricular apex to decrease the risk of apex perforation and increase wire stability. The use of a preshaped wire in the right ventricular apex might have been a better choice.

In our case, the valve seemed slightly oversized, was expulsed because of the rigidity of the asymmetrical tricuspid ring that was distorted in its longitudinal and radial axes during implantation. This pushed the SAPIEN 3 valve against the AV node, as well as toward the aortic root. Because our patient had a rigid aortic bioprosthesis valve, no distortion of the aortic root ensued. This may not have been the case with a native aortic valve. Another scenario might be a wire misalignment that directed the THV device outside the tricuspid ring during the implantation procedure. An en face view would have been useful to better appreciate the relationship between the ring and the wire position before the valve deployment.

In our case, the valve seemed slightly oversized, was probably not optimally aligned during deployment, and ended up entrapped in the open segment of the rigid ring. The rigidity, open shape, and open configuration of the ring may lead to imperfect positioning, resulting in severe PVL. Particular attention should be paid to sizing and wire position with respect to the ring while implanting the valve.

Conclusions

In our case, the valve seemed slightly oversized, was probably not optimally aligned during deployment, and ended up entrapped in the open segment of the rigid ring. The rigidity, open shape, and open configuration of the ring may lead to imperfect positioning, resulting in severe PVL. Particular attention should be paid to sizing and wire position with respect to the ring while implanting the valve.

Disclosures

The authors have no conflicts of interest to disclose.
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Supplementary Material

To access the supplementary material accompanying this article, visit CJC Open at https://doi.org/10.1016/j.cjco.2019.09.005.