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Case Report

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 that recurs after surgical ring repair. The worldwide experience remains limited. We report a case of unsuccessful transfemoral tricuspid valve-in-ring implantation (using an Edwards SAPIEN 3 valve, Edwards Lifesciences, Irvine, CA) and literature review. 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.

RÉSUMÉ

Après annuloplastie tricuspide chirurgicale, l'implantation d'une valve percutanée dans l'anneau représente une potentielle alternative a la reprise chirurgicale chez les patients a haut risque présentant une régurgitation tricuspide sévere symptomatique. L'expérience d'une telle intervention dans le monde demeure toutefois limitée. Nous rapportons un cas d'échec de l'implantation transfémorale d'une valve SAPIEN 3 (Edwards Lifesciences, Irvine, CA) dans un anneau tricuspide et nous passons en revue la littérature. La rigidité ainsi que la forme et la configuration ouverte de l'anneau peuvent conduire a une mauvaise position de la prothese valvulaire avec comme résultat une fuite paravalvulaire potentiellement sévere. Il faut porter une attention particuliere a la sélection de la taille de la prothese valvulaire et a la position du fil guide au moment de l'implantation de la valve.

Surgical reintervention after tricuspid valve surgery is known to be associated with a 30-day mortality of more than 25% in most series. Transcatheter tricuspid valve-in-ring (TVIR) implantation has emerged as a potential alternative to surgery for high-risk patients with recurrent symptomatic severe tricuspid regurgitation after surgical ring repair. However, the rigidity, open shape, and open configuration of the ring may lead to an imperfect result. We report a case of unsuccessful transfemoral TVIR implantation and literature review.

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 transprosthetic aortic gradient was 11 mm Hg, and the invasive mean pulmonary pressure was 25 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%; **Euro**pean **S**ystem for **C**ardiac **O**perative **R**isk **E**valuation [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.

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

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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.

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

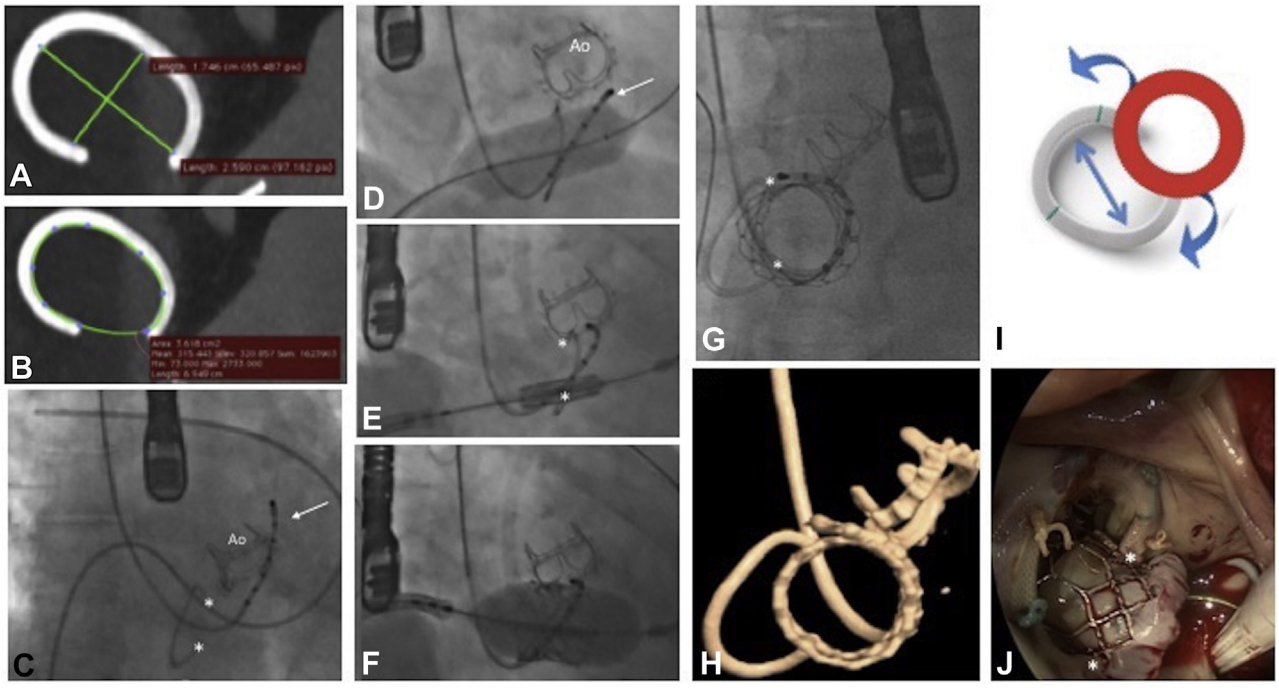

Figure 1. (**A, B**) The size of the transcatheter heart valve (THV) was selected using the ring size as a reference and the computed tomography (CT) measurement (diameters: 17.5 × 25.9 mm, area: 3.618 cm^2, perimeter: 69.5 mm, derived diameter: 23.4 mm). (**C**) Fluoroscopy showing the pacemaker lead (**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.

Table 1. Procedural characteristics and results of the published tricuspid valve-in-ring cases

	Age and sex	Ring	Valve approach	Pacing	Wire	Predilatation	PVL	Postintervention gradient
Mazzitelli et al.[1]	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.[2]	68 y, female	CE 32	XT 29 +1 cc Transfemoral	NA	PA	No	Mild	3 mm Hg
Condado et al.[3]	21 yr, female	CE 26	Melody 22 mm (Medtronic) Transfemoral	No	RV apex	Yes	PVL Severe → Mild (c)	4 mm Hg
Piliero et al.[4]	62 y, female	CE 32	XT 29 mm Transfemoral	LV apex	PA	No	Mild	5 mm Hg
Girdauskas et al.[5]	57 y, female	CE 32	XT 29 mm +2 cc Transapical	Epicardial	SVC	No	Trace	3 mm Hg
Bouleti et al.[6]	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.[7]	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[8]	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,[1] 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[2–7] 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.[8] 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. This makes sizing a challenge, because it is difficult to determine which diameter to use. Cabasa et al.[2] planned their procedure using a cardiac CT-derived 3-dimensional printed model, a strategy that could be further exploited.

Bouleti et al.[6] recommend avoiding the 23-mm Edwards SAPIEN valve to decrease the risk of a high gradient. In their series, they selected the valve with the closest diameter to the mean inner diameter of the ring. In the cases reported (Table 1), there were only two 26-mm Carpentier-Edwards rings, and all the others were larger. In one of them, a 22-mm Melody valve was implanted after balloon sizing, and for the other case, a 26-mm Edwards SAPIEN XT valve was successfully deployed. Indeed, 26-mm Edwards SAPIEN XT valves were also implanted in 30-mm and even 32-mm Carpentier-Edwards rings.

On the basis of these data and CT measurement, we thought that a 26-mm SAPIEN 3 valve would be slightly oversized; therefore, we decided to retrieve 1 mL from the balloon. In addition, as in half of the cases in the international series, we performed a balloon sizing with a 23-mm balloon, which confirmed our choice of valve size.

One possible explanation for the valve malpositioning is that the THV device was still slightly oversized and 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 bioprosthetic 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 most of the cases reported, the wire was positioned at the apex.

Rapid pacing was performed during more than half of TVIR. We think that the rapid pacing helped us to stabilise the deployment of the valve. Indeed, it was of benefit because the patient developed complete AV block immediately after valve deployment secondary to AV node compression by the THV. We decided to insert the pacemaker lead in the coronary sinus to avoid interference with the valve deployment. Pacing on the 0.035 stiff wire positioned in the right ventricular apex might be the best strategy. Indeed, during balloon valvuloplasty our pacemaker lead moved backwards (Fig. 1D), but remained functional. To better understand its relationship to the ring and THV, a CT scan showed that it passed by the side of the THV (Fig. 1H; Video 3, view video online). We did not retrieve it before surgery to avoid THV migration. Surgery confirmed the para-ring position of the THV device that was solidly anchored by the 2 extremities of the tricuspid ring entrapping the stent struts of the THV, and it required a surprisingly high amount of force to open the ring and free the THV.

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.

References

1. Mazzitelli D, Bleiziffer S, Noebauer C, et al. Transatrial antegrade approach for double mitral and tricuspid "valve-in-ring" implantation. Ann Thorac Surg 2013;95:e25-7.

2. Cabasa AS, Eleid MF, Rihal CS, et al. Tricuspid valve replacement: a percutaneous transfemoral valve-in-ring approach. JACC Cardiovasc Interv 2015;8:1126-8.

3. Condado J, Leonardi R, Babaliaros V. Percutaneous tricuspid valve-In-ring replacement for the treatment of recurrent severe tricuspid regurgitation. Catheter Cardiovasc Interv 2015;86:1294-8.

4. Piliero N, Guerbaai RA, Ennezat PV, Bouvaist H. Percutaneous tricuspid valve-in-ring implantation in a systemic sclerosis patient with pulmonary arterial -hypertension. Acta Cardiologica 2017;72:218-9.

5. Girdauskas E, Lauer B, Kuntze T. Transapical tricuspid valve-in-ring implantation: an alternative approach to a challenging clinical scenario. Catheter Cardiovasc Interv 2018;91:1005-8.

6. Bouleti C, Himbert D, Brochet E, et al. Transfemoral tricuspid valve-in-ring implantation using the Edwards Sapien XT valve: one-year follow-up. Circ Cardiovasc Interv 2015;8(3).

7. Reichart D, Shofer N, Deuschl F, et al. Transcatheter tricuspid valve-in-ring and aortic valve-in-valve implantation. Thorac Cardiovasc Surg Rep 2017;6:e29-31.

8. Aboulhosn J, Cabalka AK, Levi DS, et al. Transcatheter valve-in-ring implantation for the treatment of residual or recurrent tricuspid valve dysfunction after prior surgical repair. JACC Cardiovasc Interv 2017;10:53-63.

Supplementary Material

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