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Transcatheter Valve-in-Ring Implantation for the Treatment of Residual or Recurrent Tricuspid Valve Dysfunction After Prior Surgical Repair

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ABSTRACT

OBJECTIVES This study sought to describe the results of transcatheter tricuspid valve-in-ring (TVIR) implantation for treatment of tricuspid regurgitation (TR).

BACKGROUND Off-label use of transcatheter valves within surgically placed tricuspid annuloplasty prostheses has only been described in small reports. An international multicenter registry was developed to collect data on TVIR implantation.

METHODS Data were collected from 13 sites on 22 patients (5 to 69 years of age) with TR who underwent catheterization with the intent to perform TVIR implantation.

RESULTS TVIR implantation was performed in 20 patients (91%). Most patients were severely impaired (86% in New York Heart Association functional class III or IV); TR was severe in 86%. A Sapien valve (Edwards Lifesciences, Irvine, California) was implanted in 17 patients and a Melody valve (Medtronic, Minneapolis, Minnesota) in 3. There were no procedural deaths. There was 1 valve embolization requiring retrieval and placement of second TVIR implant and 1 valve malposition with severe paravalvular regurgitation requiring a second TVIR implantation. Over a median follow-up of 12 months, 1 patient died and 2 underwent repeat TVIR implantation, 1 of whom subsequently underwent surgical valve replacement. Significant paravalvular leak (PVL) was treated at the time of TVIR implantation in 4 patients: 3 underwent device occlusion and 1 received a second TVIR implant. On follow-up echocardiography, 15 patients had PVL (75%), the majority of which (n = 10) were trivial or mild and did not require treatment. PVL intervention was performed in 3 patients during follow-up. Functional capacity improved in most patients (70%).

CONCLUSIONS TVIR implantation using commercially available transcatheter prostheses is technically feasible and clinically effective in reducing TR. Paravalvular regurgitation is common and may necessitate further interventions. (J Am Coll Cardiol Intv 2017;10:53-63) © 2017 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

NYHA = New York Heart Association

PVL = paravalvular leak

RA = right atrial

RV = right ventricular

TR = tricuspid regurgitation

TS = tricuspid stenosis

TV = tricuspid valve

TVIR = transcatheter tricuspid valve-in-ring

TVIV = transcatheter tricuspid valve-in-valve

In recent years, there has been a growing recognition of the adverse physiologic impact of tricuspid regurgitation (TR), and a concomitant increase in surgical intervention for TR (1,2). The majority of surgical procedures for TR consist of valve repair rather than replacement (3,4). In patients with significant TR, the tricuspid valve (TV) annulus is frequently dilated and is often repaired surgically with an annuloplasty ring or band to reduce the size of the annulus and facilitate improved leaflet coaptation. Although most patients derive short-term benefit from TV repair, the longevity of such repairs is suboptimal, with more than 25% of patients developing progressive moderate or severe TR within 5 years of repair depending on various clinical and technical factors (5,6). Patients with recurrent TR following initial surgical repair are often complex and have numerous comorbidities, and thus are at high risk for adverse outcomes after TV reoperation (5,6).

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Transcatheter valve replacement is now widely utilized to treat native and post-surgical dysfunction of aortic and pulmonary valves. The off-label use of transcatheter valves for TV valve-in-ring (TVIR) implantation has been reported but the literature is limited to case reports and small case series (7–10). A larger experience exists with TV valve-in-valve (TVIV) implantation within dysfunctional surgical bioprostheses (11). There are a number of challenges inherent to TVIR implantation, including the wide variety of rings and bands that vary in size, shape, rigidity, and circumferential completeness. Whereas progressive valvular thickening and calcification often results in stenosis and may provide a reasonable landing zone for a variety of transcatheter valves in patients with dysfunctional bioprostheses (11), incomplete TV annuloplasty rings tend to develop progressive regurgitation and annular dilation, with dimensions that are often large and geometrically heterogeneous (7). Although TVIR implantation is an appealing alternative to high-risk redo open-heart surgery, little is known about the results of this procedure.

METHODS

REGISTRY. Data were collected through a registry of institutions that have performed TVIV or TVIR implantation, as described previously (11). As noted in our prior report, participating institutions were requested to submit data for successful and unsuccessful procedures in which implant was attempted, as well as for patients who underwent catheterization with the plan to place a valve but in whom implant was not attempted. The present study included all transcatheter implants in the TV position after prior repair. This study did not include TVIV procedures or heterotopic (e.g., caval) valve implants for TR. The institutional review board or ethics committee at participating centers approved submission of data.

SURGICALLY REPAIRED TV AND TVIR FUNCTION.

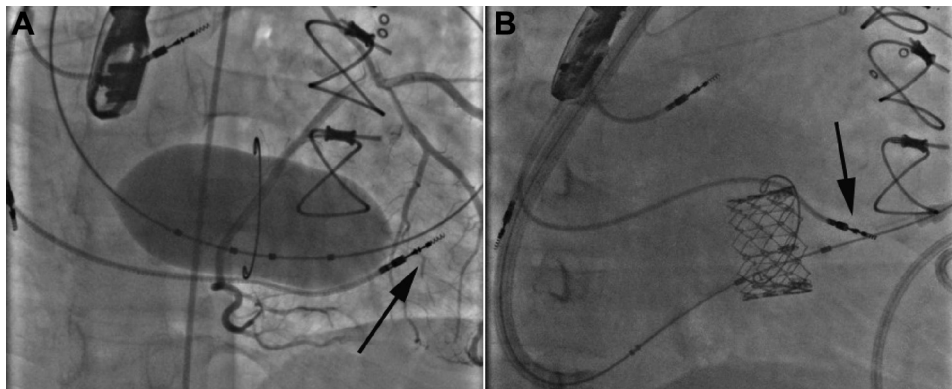
Data on TV function, including the mean TV inflow pressure gradient, TR grade, and severity of paravalvular leak (PVL), were reported by the implanting center. TR severity was graded as none, trivial, mild, moderate, or severe, based on standard criteria, and categorized as significant (moderate or severe) or less than or equal to mild. TV inflow gradients were reported in terms of the mean Doppler right ventricular RV inflow gradient and direct measurement of mean right atrial (RA) and RV pressure gradient by catheterization. Other pressure measurements collected during catheterization included the mean RA, RV systolic, and RV end-diastolic pressures. TV prosthesis dysfunction was defined as significant tricuspid stenosis (TS) or at least moderate TR on early post-implant evaluation. Recurrent TVIR dysfunction was defined as progression to significant TS or moderate or severe TR during follow-up. Significant TS was defined as a mean diastolic Doppler gradient >6 mm Hg. PVL was graded qualitatively as trivial, mild, moderate, or severe, and characterized according to location. Cross-sectional imaging with either computed tomography or magnetic resonance imaging was performed at the discretion of the treating physicians, but was not performed for most patients in this cohort so data were not reported.

TVIR PROCEDURE. TVIR procedures were performed at the discretion of the implanting physician, with

Flow Medical; and is on the advisory board for Medtronic. Dr. Makkar has served as a consultant for Abbott Vascular, Cordis, and Medtronic; and has received grant funding from Edwards Lifesciences and St. Jude Medical. Dr. Boudjemline has served as a proctor for Medtronic. Dr. Bleiziffer has served as a proctor for JenaValve, Boston Scientific, and Medtronic; and as a consultant for Medtronic. Dr. Dvir has served as a proctor and consultant for Edwards Lifesciences. Dr. McElhinney has served as a proctor and consultant for Medtronic. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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FIGURE 1 Pacemaker Lead Dislodgement Post Placement of Sapien XT in the Tricuspid Position



(A) Balloon sizing of the tricuspid valve (TV) annulus with a 30 mm balloon demonstrating a mild waist. Simultaneous right coronary angiography does not demonstrate any evidence of coronary artery compression. Note the right ventricular (RV) pacing lead in the ventricular apex (arrow). It appears that the RV lead is running external to the ring, but it is actually running through the portion of the valve adjacent to the medial open portion of the ring. (B) After transcatheter tricuspid valve-in-ring implantation with a 29-mm Sapien XT (Edwards Lifesciences, Irvine, California) from a jugular venous approach (the delivery catheter is still through the valve), the RV pacing lead is entrapped and has dislodged from the apex (arrow).

either Melody (Medtronic, Minneapolis, Minnesota) or Sapien family (Edwards Lifesciences, Irvine, California) valves. Procedural details collected included: transcatheter valve type and size; vascular access; method of intraprocedural echocardiographic imaging; site and method of rapid pacing during implant; pre-dilation or pre-stenting; post-dilation; placement of occlusion devices for treatment of PVL; procedural success; and adverse events.

DATA ANALYSIS. Due to the small sample size, analysis of data is primarily descriptive. Continuous variables were presented as median (minimum-maximal), and categorical variables as frequency (%). Outcomes of interest included technical success (TVIR implant in the intended location), acute hemodynamic results, adverse events, survival, New York Heart Association (NYHA) functional class, TVIR dysfunction or reintervention, and valve function over time. Time-related outcomes were not analyzed statistically due to the small number of patients.

RESULTS

PATIENTS. Twenty-two patients were catheterized with the intent to perform TVIR implantation. Of these, 20 (91%) underwent successful TVIR implantation. Ten patients had balloon sizing of the TV (Figure 1), and the 2 patients who did not receive a valve both had balloon testing that showed no

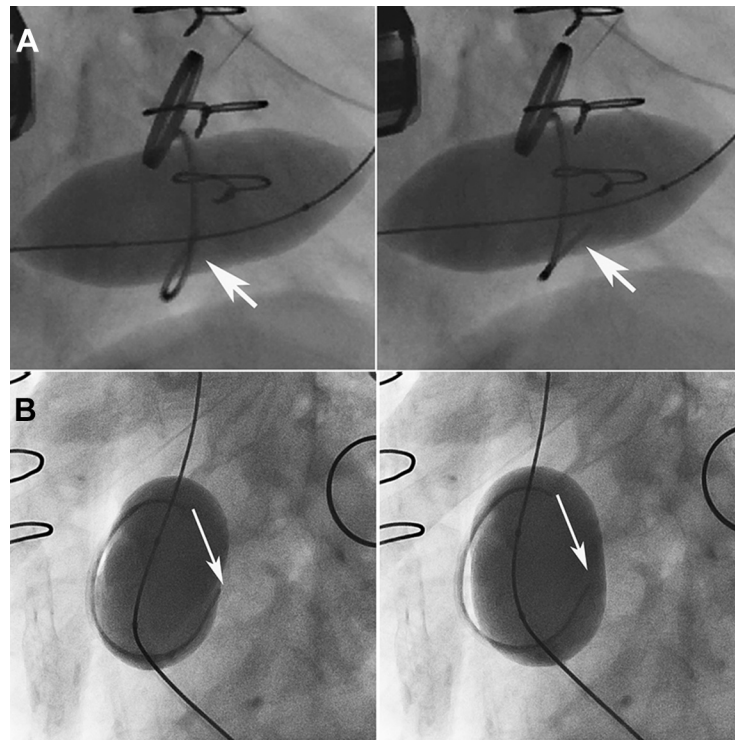
appreciable landing zone or TR through the open portion of the annuloplasty ring. In 1 of the patients who did not receive a valve, there was severe persistent regurgitation through the TV orifice that was adjacent to the open portion of the ring, as well as displacement of the ring during balloon sizing (Figure 2).

Baseline demographic and clinical data are detailed in Table 1. Patients ranged in age from 5 to 69 years. Most patients, were significantly impaired, with 86% in NYHA functional class III or IV, undergone multiple prior cardiac surgeries, and had a history of atrial arrhythmias. Six patients (27%) were acutely ill and hospitalized at the time of the intervention.

TV FUNCTION AND PRIOR REPAIR. In 45% of cases, the underlying TV disease was congenital, whereas 55% were secondary to acquired TV dysfunction. A TV annuloplasty ring had been placed as part of a surgical repair a median of 7 years prior to TVIR implantation (Table 2). The majority (50%) of rings were 30 to 32 mm, and all but 1 were open.

By pre-catheterization echocardiography, all patients had moderate or severe TR and 4 had significant TS. By invasive assessment, the RA mean pressure (median 19 mm Hg, range 7 to 25 mm Hg) was elevated.

PROCEDURAL DETAILS AND OUTCOMES. All procedures were performed under general anesthesia, mostly from a femoral venous approach (73%) with

FIGURE 2 Distortion of a Tricuspid Annuloplasty Ring During Balloon Inflation

These images are from a patient who underwent balloon sizing but did not have transcatheter tricuspid valve-in-ring implantation. Fluoroscopic images in **(A)** modified anteroposterior and **(B)** left anterior oblique projections showing the sizing balloon before it is fully inflated (**left**) and at full inflation (**right**). The **arrows** in **A** indicate the posteroinferior arm of the ring and demonstrate distortion and apical displacement of that portion of the ring during full balloon inflation. The **arrows** in **B** begin at the superior margin of the open portion of the ring, and demonstrate the change in configuration with full balloon inflation. The transesophageal echocardiographic images in **C** and **D** demonstrate the cross-sectional anatomy of the tricuspid valve ring (**left**) and the color Doppler images (**right**) show the tricuspid regurgitation jets. **(C)** The annuloplasty ring is indicated by the **arrowheads** (tricuspid valve orifice between the **arrowheads**); it is possible to appreciate a regurgitant orifice outside of the ring, both on cross-sectional and color flow imaging. **(D)** The sizing balloon is fully inflated, but there is significant persistent regurgitation medially through the portion of the TV that lies beyond the open portion of the ring. B = air bubbles.

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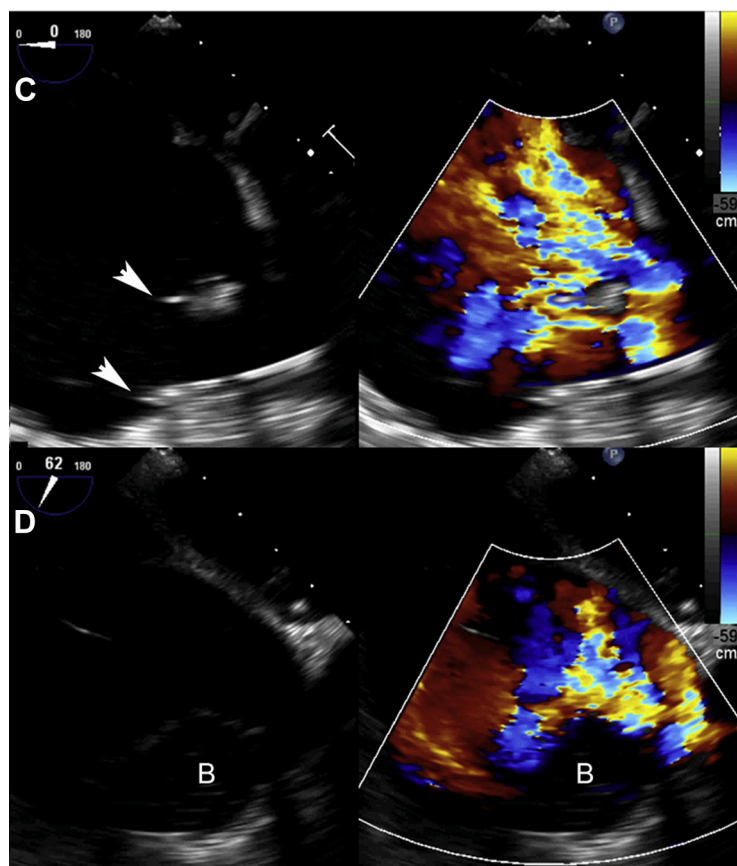
transesophageal echocardiographic guidance. A Sapien valve was implanted in 17 patients (85%), most often a 26 or 29-mm Sapien XT (80%), and a Melody valve was implanted in 3 (**Table 3**). Rapid pacing was implemented to stabilize the heart during implant in 56% of cases either via an existing pacing system (n = 9) or a temporary transvenous atrial pacing wire (n = 2). In 1 patient with D-transposition of the great arteries who had undergone an atrial switch operation, TVIR implantation was performed successfully into a systemic TV using a hybrid approach (**Figure 3**).

In 4 patients with a transvenous RV pacing lead traversing the TV annulus, the lead was entrapped by the TVIR implantation. In 1 patient, the RV lead was dislodged, although that patient did not require

ventricular pacing (**Figure 1**). Procedural complications included valve embolization in 1 patient due to distal positioning via a right atrial hybrid approach necessitating surgical retrieval and placement of second TVIR implant, and valve malposition with severe PVL that was treated with a second TVIR implant (**Table 3**).

No patients had significant TR or TS after TVIR implantation. The mean RA-RV gradient by Doppler ranged from 0 to 5 mm Hg (median 4 mm Hg). However, moderate or severe PVL requiring intervention during the index TVIR procedure occurred in 4 patients: 3 had an occlusion device placed and 1 underwent additional TVIR implantation. One patient with PVL underwent surgical tricuspid valve

FIGURE 2 Continued



replacement (TVR) 6 days post-TVIR implantation. After TVIR implantation, 18 of 20 patients were treated with antiplatelet agents ($n = 9$), warfarin ($n = 2$), or both ($n = 7$), whereas 2 did not receive therapy.

FOLLOW-UP. The overall degree of TR (including valvular TR and PVL) improved in the majority of patients after TVIR implantation. Moderate or severe TR was present in all patients pre-TVIR implantation (all valvular) and in 3 of 20 patients (15%; all PVL) after TVIR implantation. On the latest follow-up echocardiogram, a median of 12 months after implant, no patients had more than mild TR (5 mild, 10 trivial, 5 none). Improvement in functional capacity was noted in the majority of patients, from a median NYHA functional class of III pre-TVIR implantation to II post-TVIR implantation; at follow-up, only 2 patients were in NYHA functional class III or IV, compared with 19 prior to TVIR implantation. One patient was in the ICU on inotropes and continuous hemofiltration; within 24 h of TVIR implantation the

inotropes were off and within 2 weeks dialysis was no longer needed.

During a median follow-up of 12 months (range: 0.4 to 34 months), there was 1 death; a 75-year-old patient with severe TR, pulmonary hypertension, and RV failure who was on mechanical circulatory support prior to intervention. Despite successful TVIR implantation and closure of a moderate PVL with 2 occluders, the patient continued to decline and died of multiorgan failure 12 days later. In addition to the 2 patients who had a second valve placed during the index procedure, 1 other patient underwent repeat TVIR implantation during follow-up. Fifteen months after the original procedure, a 29-mm Sapien XT valve was placed for persistent PVL, but there was still residual PVL, so a third TVIR implantation was performed 10 months later (29-mm Sapien 3 device) along placement of muscular VSD occluder. Soon after this, the patient developed hemolysis and severe TS, so surgical TVR was performed. There were no episodes of endocarditis.

TABLE 1 Demographic and Diagnostic Data Among 22 Patients Catheterized for Intended TVIR Implant

Age, yrs	49 (5-69)
Etiology of original TV disease (prior to TV repair)	
Congenital	10 (45)
Ebstein's anomaly	4 (18)
Other CHD, abnormal TV or secondary TR	6 (27)
Acquired	12 (55)
Rheumatic heart disease	4 (18)
Left heart disease	3 (13)
Endocarditis	2 (9)
Pulmonary arterial hypertension	2 (9)
TV injury	1 (4)
Number of prior cardiac surgeries	2 (1-10)
Other prosthetic valves	13 (60)
Aortic	5 (24)
Mitral	9 (43)
Pulmonary	3 (10)
Comorbidities	
Acutely ill, hospitalized prior to procedure	6 (27)
Atrial fibrillation or flutter	16 (73)
Acute/chronic renal insufficiency	2 (9)
Chronic lung disease	3 (13)
Prior history of endocarditis	2 (9)
Existing permanent pacemaker	11 (50)
Epicardial	1 (4)
Transvenous	10 (45)
NYHA functional class	
I	0 (0)
II	3 (14)
III	11 (50)
IV	8 (36)

Values are median (minimum-maximal) or n (%).

CHD = congenital heart disease; NYHA = New York Heart Association; TR = tricuspid regurgitation; TV = tricuspid valve; TVIR = transcatheter tricuspid valve-in-ring.

TABLE 2 TV Function and Annuloplasty Related Data Among 22 Patients Catheterized for Intended TVIR Implant

Age of TV repair, yrs	7 (0.1-25)
≤5	11 (50)
≥10	6 (27)
Type of surgical implant	
Ring only	19 (86)
Ring with homograft/autograft	2 (9)
No ring/repared valve	1 (5)
Ring size, mm	
<30	7 (32)
30-32	11 (50)
>32	2 (9)
TR severity	
None/trivial	0 (0)
Mild	0 (0)
Moderate	3 (14)
Severe	19 (86)
Mean Doppler TV inflow gradient, mm Hg	3 (2-8)
≤5	17 (77)
6-9	4 (18)
≥10	1 (5)
Invasive pressure measurements, mm Hg	
Right atrial mean pressure	19 (7-25)
Right ventricular end-diastolic pressure	14 (6-21)
Right ventricular systolic pressure	36 (25-124)

Values are median (minimum-maximal) or n (%).

Abbreviations as in Table 1.

TVIR VALVE FUNCTION AND PVL. Fifteen patients had PVL (75%), the majority of which (n = 9) were trivial or mild and did not require treatment, whereas 4 were moderate and 2 were severe. PVLs were located in the open medial aspect of the ring in most (78%). In addition to the 4 patients who underwent early PVL treatment during the index TVIR procedure, PVL intervention was performed in 4 patients during follow-up, 2 during the same hospitalization for TVIR implantation and 2 after 11 months and 15 months post-TVIR implantation. Overall, 6 patients had 1 (n = 2) or more (n = 4) occlusion devices implanted to treat PVL, either at the index TVIR procedure (n = 3) or during follow-up (n = 4); an Amplatzer vascular plug II (St. Jude Medical, Minneapolis, Minnesota) was used in 4 patients, and an Amplatzer muscular ventricular septal occluder in 2 patients. Device closure alone successfully treated PVL in 2 patients (Figures 4 and 5). As described

previously, 1 patient underwent a total of 3 TVIR procedures and multiple device closures, but eventually was treated surgically. Another underwent surgical TVR 6 days post-TVIR implantation for PVL.

DISCUSSION

TVIR OUTCOMES AND IMPLICATIONS. This registry was undertaken to provide an overview of practices and outcomes of off-label transcatheter valve replacement for TV dysfunction after prior surgical repair. Although the majority of procedures were technically successful and resulted in reduced TR, PVL was common. Four patients underwent intervention to address PVL at the time of TVIR implantation. Although the majority of patients were NYHA functional class III or IV (90%) and 26% were acutely ill, there were no procedural mortalities. Most patients reported improvement in functional status, with sustained improvement in NYHA functional class. There were no episodes of infective endocarditis during the follow-up period.

Technically, TVIR implantation is more challenging than TVIV implantation due to the larger diameters and geometric variability of surgically placed rings. Incomplete rings, which were present in all but 1

patient, are most challenging because a circumferential landing zone is not available and therefore the risk of valve embolization and paravalvular regurgitation is higher (12). In this cohort, rapid pacing was performed in 56% of patients to reduce cardiac motion and balloon movement during valve deployment, and 2 of the 22 patients did not proceed with valve implant because of the absence of a waist on the sizing balloon. Balloon sizing prior to valve delivery was performed in 11 patients. In general, TV annuloplasty rings appear to be fairly stable landing zones, without appreciable change in geometry, although 1 of the patients who was not implanted in this series had clear apical displacement of 1 of the posterior arms of the ring during balloon sizing in addition to severe residual TR adjacent to the open portion of the ring (Figure 2). It was important to learn this prior to TVIR implantation. Discerning such changes in ring geometry, as well as residual TR, are additional potential benefits of balloon sizing. Moreover, color Doppler imaging to assess for persistent TR during balloon sizing may predict residual PVL following TVIR implantation.

Valve malposition occurred in 2 patients, including embolization in a patient who underwent a hybrid TVIR procedure via a right atrial approach and had not undergone balloon sizing prior to TVIR implantation. The valve was placed too distally and embolized to the RV.

In a recently published series of 156 TVIV implants, there were 6 problematic valve implants (4%) (11), compared with 3 (15%) in this series. This difference is likely attributable to the shorter, asymmetric, and potentially distensible “landing zone” provided by an open surgical annuloplasty ring versus the longer cylindrical and nondistensible landing zone of a bio-prosthesis (11). An additional consideration is the difficulty of properly evaluating the prosthesis size given that most rings are oval in shape with a medial opening and surrounded by valvular tissue (13). It is not surprising that PVL is common and the location is usually medial given the placement of a cylindrical stent valve platform within an open oval shaped ring. Additionally, the TV annulus may continue to enlarge at the open part of the ring which may result in new or progressive PVL during follow-up, as was noted in 4 patients in this series. Quantification of ring dimensions using electrocardiogram-gated computed tomography can be useful for sizing the ring, but does not account for the presence of valvular tissue that may alter the true dimensions (Figure 3). Thus, balloon sizing should be considered to assess the true dimensions of the ring, potential changes in geometry with expansion, and any residual TR prior to proceeding with TVIR implantation.

TABLE 3 Procedural Variables for 22 Patients Who Underwent Attempted TVIR Implant

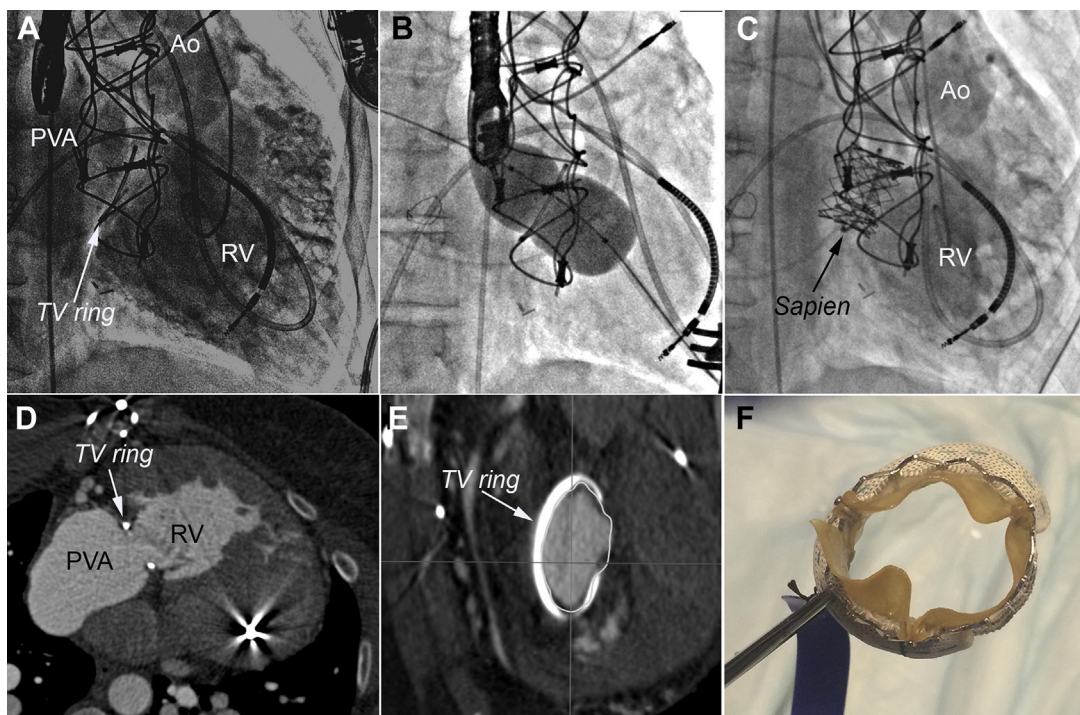
Transcatheter valve implanted	20 (91)
Transcatheter valve type	
Sapien	17 (85)
Sapien XT	13 (76)
Sapien 3	3 (18)
Sapien	1 (6)
Melody	3 (15)
Implant balloon diameter, mm	
<26	3 (15)
26	6 (30)
29	10 (50)
>29	1 (5)
Vascular access	
Femoral vein	16 (73)
Jugular vein	1 (5)
Surgical via right atrial access	2 (9)
Hybrid via right ventricular access	1 (5)
General anesthesia	22 (100)
Intraprocedural transesophageal echocardiography	22 (100)
Rapid pacing used during implant	11 (50)
Permanent pacing system	9 (41)
Temporary pacing catheter/wire	2 (9)
Pre-dilation/balloon sizing before implant	10 (45)
Ring pre-stented before TVIR	3 (15)
Valve post-dilated	5 (25)
Second valve implanted	2 (10)
Additional procedures performed at same catheterization	8 (40)
Tricuspid paravalvular leak occlusion	4 (20)
Other transcatheter valve replacement	2 (11)
Other intervention	2 (11)
Procedural complications	3 (14)

Values are n (%). Cohort who underwent TVIR, n = 20 for all patients that had a valve implanted, therefore that includes the following: Transcatheter valve type, Implant balloon diameter, Rapid pacing used during implant, valve post-dilated, ring pre-stented, second valve implant, additional procedures. n = 22 was used for vascular access, anesthesia, intraprocedural echo, pre-dilation/balloon sizing before implant and procedural complications.

TVIR = transcatheter tricuspid valve-in-ring.

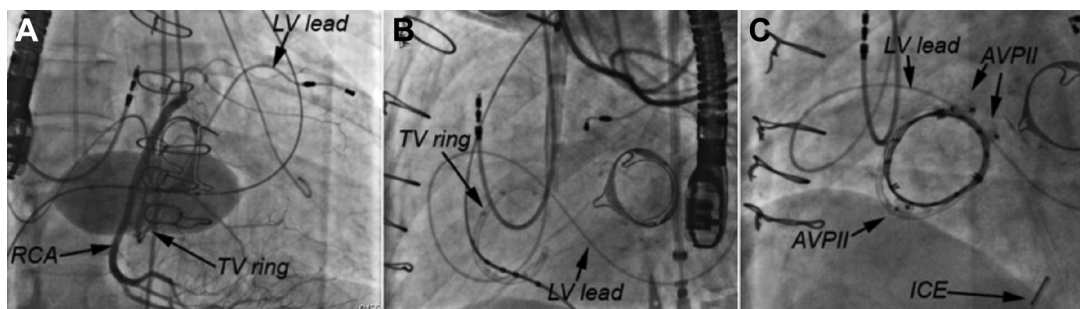
In this series, PVL was common, occurring in 15 of 20 implanted patients (75%). However, most had mild or trivial PVL. Six patients had moderate or severe PVL that required treatment, 2 of whom underwent multiple interventions for residual or new PVL. Pre-procedural cross-sectional imaging and knowledge of the ring prostheses can be useful in anticipating the need for PVL treatment after TVIR procedures. Transcatheter occlusion devices, placed either at the index procedure or later, were successful at eliminating or substantially reducing the PVL in most instances. In several cases, additional TVIR procedures and even surgical TVR were also required. Heart block was a concern due to the proximity of the conduction system to the medial tricuspid annulus, but did not occur with TVIR implantation or PVL occlusion in any of the patients that did not already

FIGURE 3 Hybrid Transcatheter Tricuspid Valve Replacement in a Patient With D-Transposition of the Great Arteries

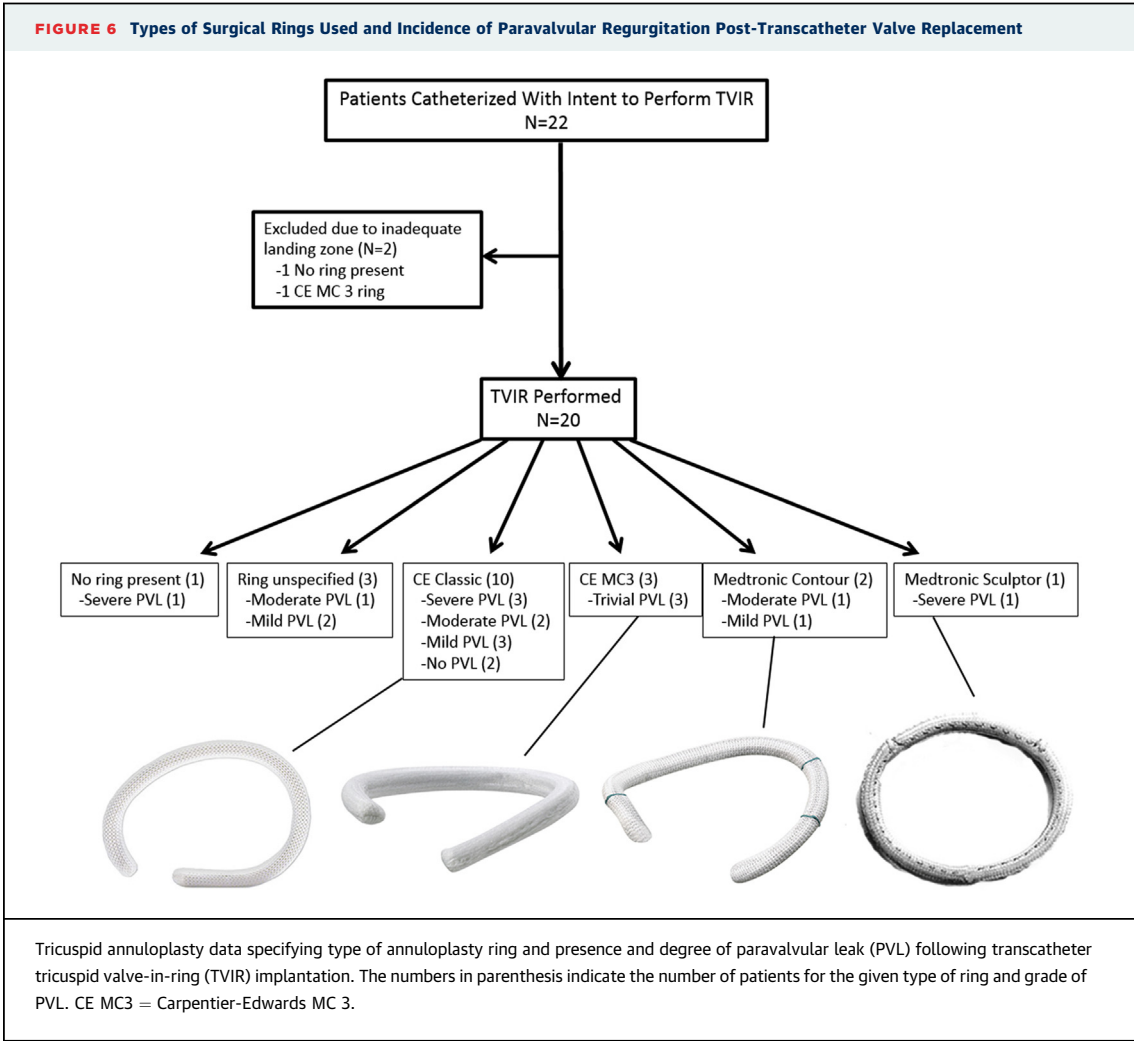
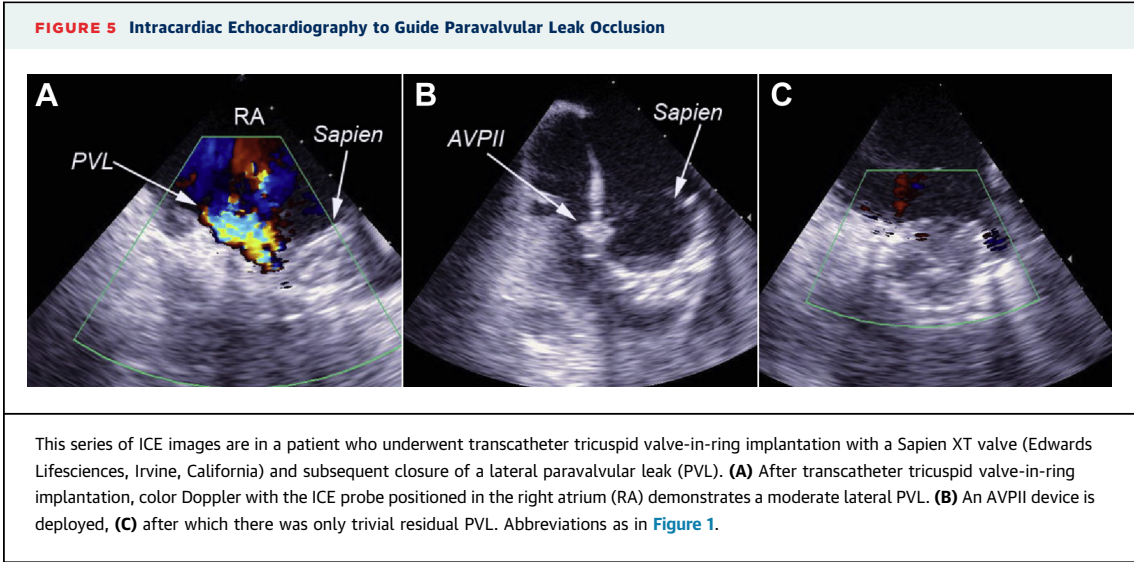


This series of images are from a patient who underwent hybrid transcatheter tricuspid valve-in-ring implantation in the systemic TV in a patient with D-transposition of the great arteries status post-atrial switch operation. **(A)** RV angiogram in the right anterior oblique projection demonstrating severe TR. **(B)** Balloon sizing of the 28-mm ring using a 30-mm balloon with a visible waist. **(C)** RV angiogram immediately following transcatheter tricuspid valve-in-ring implantation with a 29-mm Sapien XT (Edwards Lifesciences, Irvine, CA) valve delivered via the RV apex. **(D)** Axial view of electrocardiography-gated computed tomography angiogram at the level of the tricuspid annulus demonstrating severe systemic RV hypertrophy and the relationship of the RV apex to the chest wall. **(E)** Multiplanar reconstruction of the CTA demonstrating the incomplete ring en face. **(F)** Ex vivo placement of a 29-mm Sapien XT valve within a 28-mm open ring (Carpentier-Edwards MC3, Edwards Lifesciences). Ao = aorta; PVA = pulmonary venous atrium; other abbreviations as in [Figure 1](#).

FIGURE 4 Treatment of Paravalvular Regurgitation Using Vascular Plugs



These images are from a patient who underwent transcatheter tricuspid valve-in-ring implantation with 29-mm Sapien XT (Edwards Lifesciences, Irvine, California) valve who had a permanent pacing system with a right atrial lead and a LV lead through the coronary sinus. **(A)** Balloon sizing of the TV ring with simultaneous RCA angiography confirmed that there was no coronary compression (right anterior oblique projection). **(B)** The left anterior oblique view demonstrates the relationship of the coronary sinus lead (LV lead) to the TV ring. **(C)** This fluoroscopic images in a left anterior oblique projection demonstrated 3 AVPII (Medtronic, Minneapolis, Minnesota) devices used to close medial and lateral paravalvular leaks (medial leak closed at the index catheterization, lateral leak closed at a subsequent procedure) under ICE guidance. Abbreviations as in [Figure 1](#). AVPII = Amplatzer vascular plug II; ICE = intracardiac echocardiographic; LV = left ventricular; RCA = right coronary artery.



have a pre-existing pacing system. Although transient atrioventricular block was noted during placement of an occlusion device for a PVL, this resolved with repositioning of the device, and there were no cases of persistent or late heart block related to occluder placement.

In general, TVIR procedures are technically straightforward for operators who are facile in transcatheter pulmonary valve replacement and PVL occlusion. TVIR implantation can be performed via percutaneous femoral or jugular venous access, or via hybrid approaches, with favorable short- and intermediate-term results. As TVIR implantation can be used to avoid open chest surgery and cardiopulmonary bypass in a patient population with multiple comorbidities and prior sternotomies, it is reasonable to consider TVIR implantation as an alternative to high-risk surgery. A variety of commercially available surgical annuloplasty rings were present in the patients in this series (Figure 6). As TVIR implantation becomes more common, it will be imperative to gain a better understanding of which ring types and sizes are most amenable to TVIR implantation without significant PVL. Although this registry represents a limited experience, going forward, it may be worthwhile to consider potential future TVIR implantation when selecting annuloplasty rings for surgical placement.

Procedural or late adverse events other than PVL were uncommon. One patient had dislodgement of a ventricular pacing lead but was not dependent on ventricular pacing, and the other 3 patients with entrapped RV leads did not have documented lead malfunction. During follow-up, there were no cases of valve thrombosis or endocarditis, and no patients had more than mild TR. More patients and longer follow-up will be necessary to achieve deeper insight into risk factors for valve-related adverse events in all patients undergoing TVIR implantation.

STUDY LIMITATIONS. Data for this study were collected as part of a voluntary, unsponsored registry with self-reporting of data, no core labs, no prospective protocol for evaluation of hemodynamic outcomes, and no auditing of data. These practical limitations constrain the conclusions that can be drawn from this study. Also, some potentially relevant predictor variables, such as RV function, were not ascertained. Although we solicited participation in the registry widely, invitations were not universally accepted, including a number of previously reported cases, and there were undoubtedly TVIR implants of which we were unaware, which may introduce selection bias.

CONCLUSIONS

TVIR implantation can be performed in surgically repaired tricuspid valves across a wide range of ring sizes and types, patient ages, and underlying cardiovascular conditions. The findings of this study support TVIR implantation as a clinically useful intervention in many cases, even in patients with severe symptoms and comorbidities. Given the hemodynamic and clinical improvement and the low incidence of adverse events, it is reasonable to conclude that the risk-benefit profile of TVIR implantation is generally favorable and the risk of mortality or major morbidity is significantly lower than with surgical reintervention. PVL is common, especially in patients with incomplete rings, and often requires treatment with occlusion devices. Nevertheless, ongoing data collection, patient follow-up, and further work will be necessary to determine long-term valve function and to define specific risk factors for poor outcome.

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PERSPECTIVES

WHAT IS KNOWN? Surgical TV repair is associated with a high risk of progressive valve regurgitation. Surgical reoperation to re-repair or replace the TV carries a high morbidity and mortality risk.

WHAT IS NEW? Commercially available transcatheter balloon-expandable valves can be utilized to replace the TV by inflating the TV within the existing annular ring. This manuscript details a multicenter experience in TVIR replacement. None of the patients died and the degree of TR was significantly reduced. However, paravalvular regurgitation is common post transcatheter valve replacement and often requires transcatheter treatment with occlusion devices.

WHAT IS NEXT? Although this registry represents a limited experience, going forward it may be worthwhile to consider potential future TVIR when selecting annuloplasty rings for surgical placement.

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