

STATE-OF-THE-ART REVIEW

# Transcatheter Tricuspid Valve-in-Valve and Valve-in-Ring Implantation for Degenerated Surgical Prosthesis



Saurabh Sanon, MD,<sup>a</sup> Allison K. Cabalka, MD,<sup>b</sup> Vasilis Babaliaros, MD,<sup>c</sup> Charanjit Rihal, MD,<sup>b</sup> Sameer Gafoor, MD,<sup>d</sup> John Webb, MD,<sup>e</sup> Azeem Latib, MD<sup>f</sup>

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**CME/MOC/ECME Objective for This Article:** Upon completion, the reader should be able to: 1) discuss the principals of transcatheter tricuspid valve intervention; 2) discuss the procedural planning regarding transcatheter valve-in-valve/ring implantation; and 3) identify the complications of transcatheter tricuspid valve intervention.

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From the <sup>a</sup>Department of Integrated Medical Science, Florida Atlantic University and Tenet Health, Boca Raton, Florida; <sup>b</sup>Division of Cardiology, Mayo Clinic, Rochester, Minnesota; <sup>c</sup>Division of Cardiology, Emory University, Atlanta, Georgia; <sup>d</sup>Department of Cardiology, Swedish Heart and Vascular Center, Seattle, Washington; <sup>e</sup>Division of Cardiology, St. Paul Hospital, Vancouver, British Columbia, Canada; and the <sup>f</sup>Department of Cardiology, Montefiore Medical Center, New York, New York. Dr. Sanon is a consultant and proctor for Edwards Lifesciences and Medtronic; and is a consultant to Boston Scientific, Abbott Vascular, and Baylis Medical. Drs. Latib and Webb are consultants for Medtronic and Abbott Vascular. Dr. Gafoor is a consultant and proctor for Medtronic and Boston Scientific; and is a consultant to Abbott Vascular. Dr. Babaliaros is a consultant to Edwards Lifesciences and Abbott

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## ABSTRACT

With explosive growth in the field of transcatheter therapies in recent years, transcatheter valve-in-valve implantation has rapidly emerged as a viable, low-risk alternative to high-risk redo surgical interventions. The authors review the fundamental clinical principles of transcatheter tricuspid valve-in-valve and valve-in-ring implantation as pertinent to the procedural steps and technique. (J Am Coll Cardiol Intv 2019;12:1403-12) © 2019 by the American College of Cardiology Foundation.

**T**ricuspid valve prostheses are generally considered to have less longevity than systemic valvular prostheses (1-3). Transcatheter tricuspid valve-in-valve (TVIV) and valve-in-ring (TVIR) implantation has emerged as a viable therapy for a failed tricuspid bioprosthesis, with encouraging outcomes (4). This is particularly attractive because of the safety profile and success rate of TVIV and TVIR in contrasted with the escalated surgical risk associated with redo tricuspid surgery, especially in the setting of right ventricular (RV) dysfunction, which is frequently associated with a failed tricuspid prosthesis (5-8). The fundamental principles, clinical considerations, and procedural techniques of TVIV and TVIR are reviewed in this paper.

## TVIV AND TVIR IMPLANTATION

**PRE-PROCEDURAL PLANNING.** Much of the success of transcatheter valve procedures depends upon meticulous pre-procedural planning. Such planning should include transesophageal echocardiography to determine the mode of surgical prosthesis failure, establish stability of the surgical prosthesis, evaluate for the presence of paravalvular leak, and exclude underlying infective endocarditis. Computed tomographic (CT) imaging is important in cases of unknown surgical prostheses or rings, and this is described subsequently in further detail.

**ACCESS.** The first-in-human TVIV experience was described by Van Garsse et al. (9) in 2011 using an

Edwards SAPIEN valve (Edwards Lifesciences, Irvine, California) delivered via the internal jugular approach. Since then, the TVIV experience has expanded to include the Melody valve (Medtronic, Minneapolis, Minnesota) and newer-generation Edwards SAPIEN XT and SAPIEN 3 valves. Three routes of implantation are commonly described: 1) transfemoral; 2) transjugular; and 3) transatrial (or a hybrid approach using a thoracotomy). In general, for more vertically oriented tricuspid valves, the transfemoral approach is preferred to allow easier crossing and more coaxial deployment (10). However, with the newer, more directable and flexible valve delivery systems, transfemoral delivery appears to be feasible in most cases because it allows one to overcome the acute angle between the inferior vena cava and the tricuspid valve. For extremely horizontal tricuspid valves, the transjugular approach, although not routinely used, may allow easier achievement of coaxiality, and it may also enable the procedure in cases with an occluded inferior vena cava. We recommend that the choice of access be determined on a case-by-case basis depending upon the particular patient's anatomy. Although direct transatrial implantation has been previously described (11,12), we believe that because of the invasive nature of this approach, this should be reserved as last-line access in selected cases in which the transfemoral and transjugular approaches have been carefully considered and deemed unsuitable.

**ANESTHESIA.** In most cases, TVIV can be performed using conscious sedation and local anesthesia with

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**HIGHLIGHTS**

- TVIV implantation is an attractive alternative to high-risk redo surgery.
- The authors discuss the procedural technique and principles of TVIV implantation.
- Selection of transcatheter valve type should be individualized.

transthoracic or intracardiac echocardiographic guidance. Fluoroscopy provides landmarks for valve-in-valve positioning and guidance during deployment, and echocardiography provides assessment of the valve before and after TVIV or TVIR. Rarely is transesophageal echocardiography necessary, in which situation general anesthesia will be necessary.

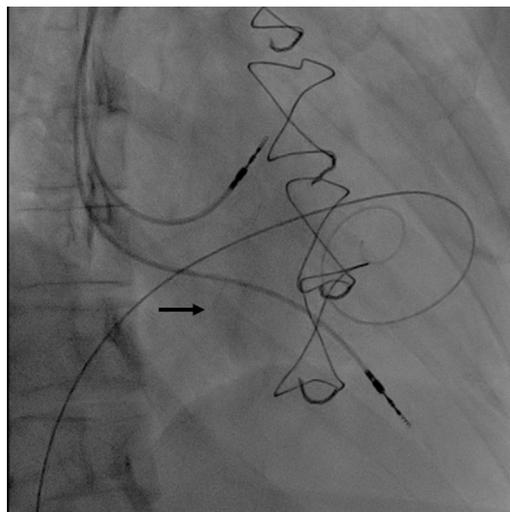
**CROSSING THE TRICUSPID PROSTHESIS.** Crucial to success in TVIV or TVIR implantation is crossing the failed surgical prosthesis. This can prove to be particularly challenging in cases in which the predominant mode of failure of the prosthesis is stenosis or in cases with severe regurgitation and a giant right atrium. Fluoroscopy is usually sufficient in guiding valve crossing for TVIV. Coplanar angles need to be identified on fluoroscopy that display the prosthesis in “end-on” and “en face” views. Typically, a physician-directed catheter such as Multipurpose is preferred, in combination with a shaped wire to direct the catheter tip, rather than the use of a balloon-tipped flow directed catheter. Steerable sheaths

such as the medium curve Agilis NXT (St. Jude Medical, St. Paul, Minnesota) or Dexterity (Spirus, Bridgewater, Massachusetts) are useful in crossing the prosthesis in challenging cases and maintaining secure catheter positioning in situations in which a primary deployment of guidewire into apex of a large right ventricle is planned. Through

**ABBREVIATIONS AND ACRONYMS**

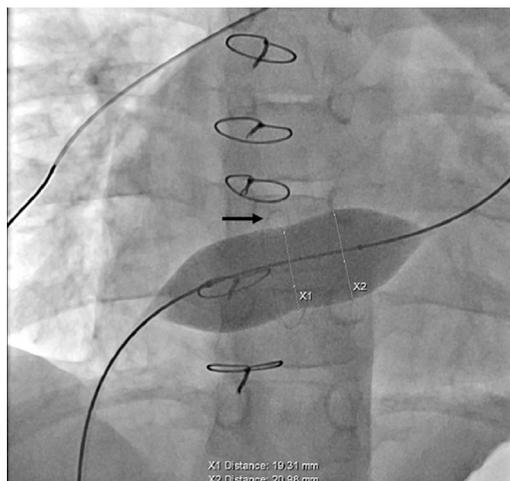
- PA** = pulmonary artery
- THV** = transcatheter heart valve
- TVIR** = transcatheter tricuspid valve-in-ring
- TVIV** = transcatheter tricuspid valve-in-valve

**FIGURE 2** A 0.035-Inch Stiff Guidewire With a Preformed Ventricular Curve Used to Create a Right Ventricular Loop for Valve Delivery



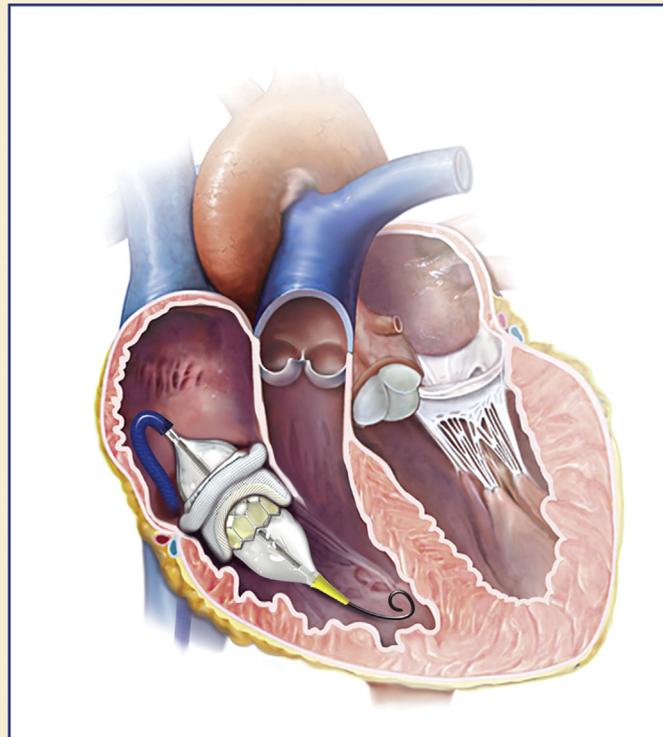
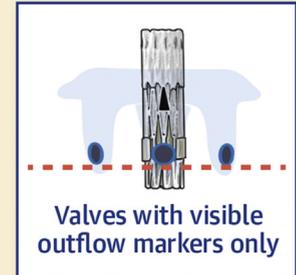
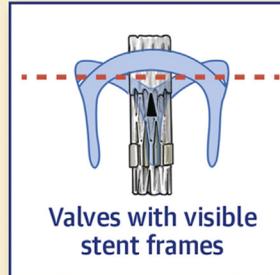
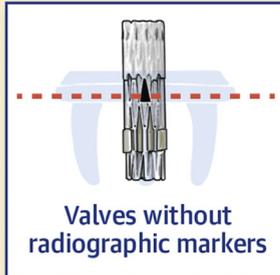
Arrow points to the radiolucent ring of an Epic/Biocor valve.

**FIGURE 3** A 22-mm Z-MED II Balloon Is Typically Used for Sizing the Existing Prosthesis and Profiling the Waist of the Valve Prior to Melody Valve Implantation



Arrow points to the Biocor/Epic valve ring.

**CENTRAL ILLUSTRATION** Transcatheter Tricuspid Valve-in-Valve Implantation



**Access**

Transfemoral

*\* Consider transjugular in case of occluded IVC*

**Anesthesia**

Conscious sedation

*\* Consider general anesthesia in selected cases*

**Imaging**

Pre-procedural TTE

*\* Consider CT for rings and unknown valve types*

**Implant**

Melody or Sapien 3 valve via RV wire loop or PA wire

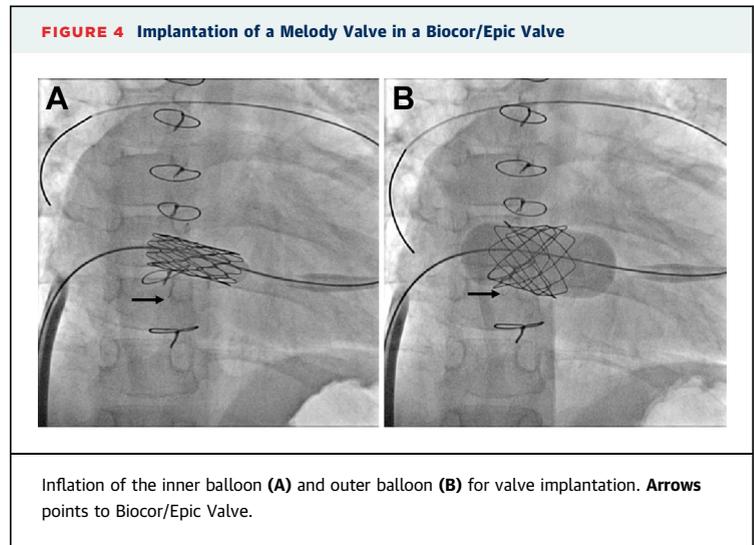
*\* Guided by echocardiography and fluoroscopy*

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the steerable sheath, we recommend using a 0.035-inch exchange-length stiff-angled Glidewire (Terumo Interventional Systems, Somerset, New Jersey) directed using 1 of the following catheter systems: 1) a standard 0.035-inch compatible balloon wedge catheter; 2) a 6-in-5 telescoping multipurpose catheter set (5-F, 125-cm multipurpose diagnostic catheter inside a 6-F, 100-cm multipurpose guide); or 3) a 6-F, multipurpose diagnostic or guide catheter. The telescoping catheter system is particularly useful in cases with challenging patient anatomy. Once the prosthesis is crossed, the operator has the option of using 1 of 2 wire positions: 1) RV loop; or 2) pulmonary artery (PA) wire position. To achieve a PA wire position, once the Glidewire is in the distal PA branch, the catheter is tracked over it and parked deep in this vessel. The left PA is generally preferred because it provides a more coaxial rail for delivery of the transcatheter heart valve (THV). Once stable position of the catheter is achieved, the Glidewire is exchanged for an exchange-length 0.035-inch Amplatz Super Stiff guidewire with a 3.5-cm flexible tip (Boston Scientific, Marlborough, Massachusetts) (Figure 1) or a 0.035-inch double-curved Lunderquist wire (Cook Medical, Bloomington, Indiana). Care must be taken to prevent inadvertent injury to the PA by the stiff guidewire. An alternative to leaving the guidewire in the PA is to use a primary RV wire loop. The RV apical wire technique will require a steerable sheath to maintain catheter position in the RV apex during advancement of a stiff wire with a preformed ventricular loop such as the Safari wire with an extra small or a small curve (Boston Scientific) or a Confida wire (Medtronic) (Figure 2). Although using an RV wire loop may be preferable to allow better coaxiality of the THV, this technique typically requires a dilated right ventricle to accommodate the wire loop. Additionally, a large right ventricle can make formation of a PA rail difficult and should prompt the use of an RV wire loop primarily.

#### VALVE SELECTION, SIZING, AND POSITIONING.

The success of a valve-in-valve procedure is incumbent on accurate identification of the surgical prosthesis, THV sizing, and precise positioning of the implant. Meticulous multimodality imaging is essential to determine valve sizing. Examining the surgical implant card or surgical note is important as a starting point to determine the true internal diameter and stent internal diameter. Thereafter, detailed CT imaging should be considered on a case-by-case basis. This is especially important in case of TVIR implantation and in cases of unknown surgical valve sizes or uncommon rings; however, it can



provide additive information even in cases of TVIV implantation. The Valve-in-Valve app (13) can be used to guide THV size selection and positioning; however, the final determination should be made on the basis of a detailed review of the patient's CT images. In case of TVIR, balloon sizing and CT sizing become very important in selecting the appropriately sized THV. Valve selection should be guided by patient's anatomy and the size of the surgical prosthesis. In general, the Melody valve may be preferable for a surgical bioprosthesis outer diameter of  $\leq 25$  mm and the SAPIEN for a surgical bioprosthesis of  $\geq 29$  mm, with room for overlap between dimensions or depending on the results of balloon sizing during the procedure. The Melody valve has an implant inner diameter of 22 mm (outer diameter 24 mm when implanted on a 22-mm delivery system). The Edwards SAPIEN 3 valve is available in sizes up to 29 mm, and its newer frame geometry with longer leaflets and a taller stent height allow overexpansion, with a resultant maximal diameter up to 31 mm with an additional 4 ml volume in the balloon (14). If overexpanding the SAPIEN 3 THV is required, special consideration must be given to valve positioning, taking into consideration the stent frame foreshortening, which is accentuated with overexpansion of the valve. If a SAPIEN 3 valve is selected for TVIV and TVIR, it becomes crucial to mount the valve for antegrade delivery onto the delivery catheter and introduce the valve delivery system with the Edwards E logo facing downward. This orientation needs to be maintained to allow the flexion of the catheter to be directed appropriately. If a Melody valve is selected, it is mounted in the standard fashion as for

<b>TABLE 1 Physical and Fluoroscopic Characteristics of Common Rings and Bands</b>			
	<b>Rigid</b>	<b>Semirigid</b>	<b>Flexible</b>
Incomplete rings	Edwards Classic  Sorin Annuloflo† 		
Incomplete bands			Medtronic Simulus  Edwards Cosgrove  Duran AnCore (Medtronic)  St. Jude Tailor Band*  Sorin Sovering† 

*Continued on the next page*

antegrade transcatheter pulmonary valve implantation. For Melody implantation, we would typically perform balloon sizing of the existing bioprosthesis with a 22-mm diameter Z-MED II balloon (Nu-Med, Hopkinton, New Jersey) to profile the waist of the valve prior to implantation (Figure 3).

In cases in which crossing the surgical prosthesis is proving difficult, one of the following maneuvers can

be used to facilitate valve delivery: 1) The SAPIEN 3 delivery catheter pusher can be retracted to make the distal part more flexible, which may allow successful tracking. 2) The SAPIEN 3 delivery balloon can be slightly inflated to allow smoother tracking of the system in cases in which there may have been a “catch” at a distal point of the delivery system. 3) Although rare, in certain severely stenotic

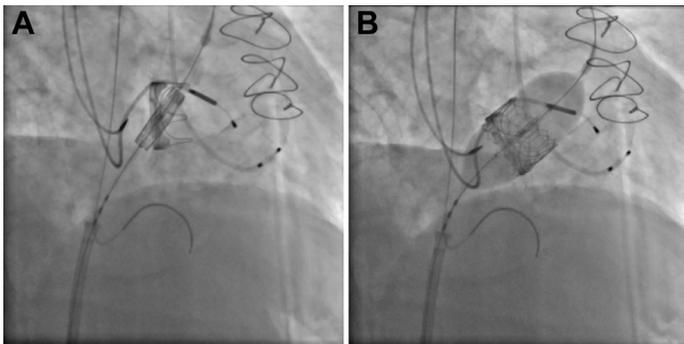
<b>TABLE 1 Continued</b>			
	<b>Rigid</b>	<b>Semirigid</b>	<b>Flexible</b>
Complete rings	Edwards Myxo (discontinued) Edwards Geoform (discontinued) Edwards IMR ETlogix	St. Jude Seguin*	St. Jude Tailor*
			
	Medtronic Profile 3D	St. Jude Rigid Saddle*	Duran AnCore (Medtronic)
			
		Medtronic Simulus Semi Rigid	
			
		Medtronic CG Future	Sorin Sovering†
			
		Sorin Annuloflex†	
			
		Sorin 3D Memo†	
			
	Edwards Physio 2		
			
	Edwards Physio 1		
			

All of the above have distinct fluoroscopic signatures except the St. Jude Seguin band, which is radiolucent. \*St. Jude Medical (Saint Paul, Minnesota). †LivaNova (London, United Kingdom).

prostheses, it may become necessary to predilate using an appropriately sized valvuloplasty balloon. Generally, an undersized balloon is safe and effective for the purpose of enabling THV delivery.

For surgical prostheses with a visible stent frame, the central marker of the SAPIEN 3 valve should be aligned 3 to 5 mm below the base (ventricular) of the surgical valve stent frame. For surgical valves with

**FIGURE 5** Implantation of a SAPIEN 3 Valve in a Perimount Valve



**(A)** The initial canted angle of the Edwards SAPIEN 3 transcatheter valve within the surgical tricuspid prosthesis prior to deployment. The valve often pivots around the anterior-most strut of the surgical tricuspid prosthesis. **(B)** Ideal coaxial alignment of the transcatheter valve at deployment.

only visible outflow markers, the outflow of the crimped SAPIEN 3 valve should be aligned 2 mm below (ventricular) the surgical valve outflow markers. Finally, for surgical valves with no radiopaque markers, the base of the central SAPIEN 3 marker should be aligned with the annular plane (**Central Illustration**). If performing TVIR, the central marker of the SAPIEN 3 prosthesis should be aligned 2 mm ventricular to the annular ring. For optimal SAPIEN 3 functioning, no more than 15% to 20% of the valve should be atrial after deployment. The Melody valve is typically implanted with inflation of the inner balloon, and the valve position is adjusted so it can be deployed with about 40% of the stent frame on the right atrial side. Inflation of the outer balloon then delivers the valve into the existing tricuspid valve. Post-dilation is not usually necessary (**Figures 4A and 4B**).

In cases of TVIR implantation, it should be determined whether the prosthesis is a ring or a band, whether it is complete or incomplete, and whether it is a flexible, rigid, or semirigid prosthesis. Incomplete rings and bands in general present a more challenging scenario with regard to THV anchoring. Balloon sizing and CT sizing are incrementally important for THV size selection for TVIR. Pacing should be given consideration for valve stabilization during TVIR deployment. Flexible rings and bands may expand during THV deployment, and hence greater oversizing should be considered. Rigid and semirigid bands and rings do not tend to expand; however, they pose a greater chance of THV

deformation and perileak. Incomplete flexible rings and bands pose the greatest risk for valve embolization, and therefore ample caution is needed prior to embarking on TVIR in such prostheses. **Table 1** lists physical and fluoroscopic characteristics of common rings and bands.

Once the THV is positioned appropriately across the surgical prosthesis, it should be deployed in a slow and controlled fashion to allow the first operator to adjust the THV position as needed. The SAPIEN 3 THV often makes contact with the anterior-most surgical strut initially, and the system pivots around that contact point to achieve coaxiality during deployment (**Figures 5A and 5B**). This is more pronounced when the valve is deployed over a PA wire position as opposed to an RV loop. In most cases, a slow and controlled inflation of the valve along with gentle rail manipulation allows opportunity for the system to achieve coaxiality.

**JAILING PACEMAKER LEADS.** It is generally accepted that jailing pacemaker leads is usually well tolerated during TVIV and TVIR (15,16). If a pacemaker lead is jailed, particular attention needs to be paid to the presence and extent of perileak along the lead. Generally, a perileak due to a lead is not clinically significant and is well tolerated. If there is any suggestion of lead dysfunction on the basis of early testing after deployment, or if the patient is dependent on the jailed pacemaker lead, we recommend that the jailed RV lead to be monitored using an accelerated impedance and threshold surveillance protocol.

**VALVE STABILIZATION DURING DEPLOYMENT.** Although majority of TVIV deployments can be successfully performed without the need for pacing, pacing may be considered on a case-by-case basis to stabilize the valve during deployment. This is usually necessary when there is excessive cardiac motion noted during TVIV or in the cases of TVIR. Many patients have pre-existing permanent pacemakers, and in such cases a wireless programmer can be used for pacing. Otherwise, this can be achieved by pacing in the right atrium or the coronary sinus. Alternatively, pacing can be performed using an uncoated 0.014-inch coronary guidewire placed in the septal perforator. Wires traditionally used for this purpose include a 0.014-inch Hi-Torque Traverse coronary guidewire (Abbott Vascular, Santa Clara, California). If using some of the newer hydrophilic coated wires, it may be necessary to shave off the hydrophilic coating at the distal stiff end of the wire to allow it to be conductive. Pacing can also be driven using a left

ventricular or RV wire on which a left ventricular curve has been shaped or a pre-formed ventricular wire such as the Safari (Boston Scientific). Additionally, novel bipolar pre-shaped left ventricular pacing wires are in development and may be available for use in the future (17). In both these pacing techniques, the pacing circuit must be completed by connecting one pacing clamp to the pacing wire and the other clamp on a needle carefully introduced into the subcutaneous tissue. Care must be taken to ensure that there are no short circuits in the pacing circuit.

**PERILEAK CLOSURE CONSIDERATIONS.** Infrequently, operators may encounter potential TVIV candidates with a combination of prosthetic pathology and periprosthetic regurgitation. In such cases we recommend first establishing stability of the prosthetic implant by detailed transesophageal echocardiographic imaging, with consideration of CT imaging on case-by-case basis. Once the prosthesis is determined to be well seated and stable, perileak closure can be offered using appropriately selected and sized closure devices. If more than 1 closure device is anticipated for successful closure, it becomes important to use an RV anchor-wire technique as a rail to allow sequential delivery of nested closure devices. We recommend that perileak closure be performed prior to TVIV implantation to minimize the chance of inadvertently crossing through the perileak into a THV cell, which would lead to unwanted positioning and interaction of the closure device with the THV. TVIR implantation presents a unique set of considerations (18). Most surgical tricuspid rings are incomplete in order to minimize impact on the conduction system. In addition, most rings are rigid, and trying to conform a round THV to a rigid oval ring presents unique concerns with regard to optimal THV leaflet function as well as development of perileak. Perileak is hence more commonly encountered after TVIR as opposed to after TVIV, and the operator needs to be prepared to address this as needed.

**POST-PROCEDURAL MANAGEMENT.** Many patients can be safely discharged home the same day, but if a decision is made to admit the patient overnight, transthoracic echocardiography can be obtained on post-operative day 1 to evaluate RV function, rule out pericardial effusion, and evaluate the baseline function of the THV. In the absence of any procedural related vascular complications, warfarin should be

promptly started on the evening of the procedure and continued for at least 3 months, ideally lifelong if tolerated, because of lower right-sided flows and consequently higher propensity for valve thrombosis or dysfunction in this position. Aspirin is recommended on a lifelong basis, as is infective endocarditis prophylaxis. Patients should be followed up at 30 days, 6 months, and annually for clinical and transthoracic echocardiographic surveillance.

## OUTCOMES

Multiple studies have now demonstrated that TVIV or TVIR implantation is technically feasible, with clinically successful outcomes (4,18-20). McElhinney et al. reported a procedural success rate of 98.6%, few serious complications, symptom improvement to New York Heart Association functional class I or II in 77% patients (13.3-month median follow-up), and no differences in outcomes irrespective of surgical valve size or transcatheter valve type. Another study reported a cumulative 3-year incidence of death, re-intervention, and valve-related adverse outcomes at 17%, 12%, and 8%, respectively (4). Although long-term data are unavailable, the midterm data appear encouraging for TVIV and TVIR as a viable therapy in degenerated tricuspid prosthesis using either the SAPIEN 3 or Melody valve.

## CONCLUSIONS

TVIV and TVIR implantation is a safer alternative to redo tricuspid valve surgery and can be performed with a high technical success rate and clinical efficiency. Though currently off-label, the Edwards SAPIEN 3 valve appears to be a good choice for this indication considering the large sizes of surgical tricuspid valves, the wide range of nominal sizes of the SAPIEN 3 valve, and the ability of this valve to function well despite oversizing (14,21). For younger patients or smaller valve sizes, the Melody valve may afford larger effective orifice areas and may be preferable. Ultimately, the valve type selected needs to be individualized to the patient's clinical and unique anatomic characteristics.

**ADDRESS FOR CORRESPONDENCE:** Dr. Saurabh Sanon, Palm Beach Gardens Medical Center, 3370 Burns Road, Suite 103, Palm Beach Gardens, Florida 33410. E-mail: [saurabhsanon@gmail.com](mailto:saurabhsanon@gmail.com).

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**KEY WORDS** transcatheter tricuspid valve implantation, tricuspid valve, valve-in-ring, valve-in-valve



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