

The Next Frontier of Percutaneous Tricuspid Valve Repair

The development of percutaneous techniques as an alternative to surgical treatment.

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Secondary to left-sided heart disease or pulmonary hypertension, functional tricuspid regurgitation (TR) without organic valvular disease is the most frequent condition affecting the tricuspid valve in Western countries.¹ This condition is common in patients with left-sided myocardial or valvular disease (approximately 50% of patients with mitral regurgitation also have concomitant TR); a significant number of patients undergoing surgery for aortic and/or mitral valve disease develop significant TR over time.^{2,3} The current prevalence of moderate-to-severe TR is approximately 1.6 million in the United States,⁴ with only a small proportion treated, resulting in a large number of untreated patients despite the known association between TR and mortality.^{5,6}

For many years, it was thought that TR would improve after surgical aortic and/or mitral valve repair. However, if untreated at the time of left-sided valve surgery, residual functional TR negatively affects perioperative outcomes, functional class, and survival,⁷⁻⁹ and therefore current European guidelines recommend concomitant surgical correction for patients with mild- to moderate-functional TR when the tricuspid annulus (TA) is dilated (> 40 mm or > 21 mm/m²).¹⁰ Surgery for TR in patients already treated with mitral and/or aortic surgery has a high in-hospital and long-term mortality rate, and a proportion of patients have residual TR or develop recurrent TR after tricuspid valve repair.¹¹⁻¹³

Considering the high-risk profile of patients with functional TR, it would be extremely attractive to find less-invasive options for its management. In the last few years, novel transcatheter treatments for treating TR have begun development, offering a potential alternative to surgery.

ETIOLOGY AND PATHOPHYSIOLOGY OF TRICUSPID REGURGITATION

Approximately 8% to 10% of all TR is primary. The etiology of primary TR includes congenital abnormalities, rheumatic fever, trauma, infective endocarditis, myxomatous degeneration, and iatrogenic causes (after pacemaker implantation or right ventricular biopsy). The large majority of TR is secondary to conditions that cause right ventricular dilatation, including left-sided heart disease and pulmonary hypertension (Table 1).¹⁴

The pathophysiology of secondary or functional TR can be divided into three phases.¹⁵ In the first phase, the initial dilation of the right ventricle causes dilation of the TA; in this phase, some degree of TR is present. In the second phase, the progressive dilation of the right ventricle and of the TA leads to a progressive, significant TR due to the lack of leaflet coaptation. Last, the progressive distortion of right ventricular geometry is associated with tethering of the leaflets and a subsequent worsening of the regurgitation.^{16,17} The anterior and posterior leaflets, which are anchored to the free wall of the right ventricle, progressively move away from each other creating dilation of the TA along its anteroposterior plane. The septal cusp, anchored to the fibrous skeleton, is only partially involved in the dilation of the TA.

ANATOMICAL COMPLEXITY: A PROBLEM FOR PERCUTANEOUS TREATMENT OF THE TRICUSPID VALVE

Several anatomical factors may represent a challenge for the percutaneous treatment of TR. The enlarged TA (> 40 mm), the fragility of the annular and leaflet tis-

TABLE 1. ETIOLOGY OF TRICUSPID REGURGITATION

Classification		Specific Abnormalities
Primary	Congenital	• Ebstein anomaly
	Acquired disease	• Carcinoid • Degenerative (myxomatous) • Endocarditis • Endomyocardial fibrosis • Iatrogenic (pacemaker, right ventricular biopsy) • Rheumatic • Toxic • Traumatic • Ischemic (papillary muscle rupture)
Secondary	Left side disease	• Left ventricular dysfunction • Valvular pathology
	Right ventricular dysfunction	• Right ventricular cardiomyopathy (eg, arrhythmogenic dysplasia of the right ventricle) • Right ventricular ischemia • Right ventricular volume overload
	Pulmonary hypertension	• Chronic pulmonary disease • Left-right shunt • Pulmonary thromboembolism
	Right atrial abnormalities	• Atrial fibrillation

sue as compared to the mitral valve, and the absence of calcium undoubtedly represent the main difficulties for performing in-human transcatheter tricuspid valve repair or replacement. The introducer sheath and the delivery system should accommodate a prosthesis twice the size of the prostheses utilized for transcatheter aortic valve replacement. Furthermore, the angle between the TA and superior or inferior vena cava (IVC) and the right ventricular trabeculae represent a further challenge. The thin wall of the apex of the right ventricle and the presence of multiple chordae make the transapical approach very difficult. Finally, the adjacent structures, such as the atrioventricular node and bundle of His, coronary sinus, the right coronary artery, and the right ventricular outflow tract need to be considered.

Percutaneous Treatment of Tricuspid Regurgitation

Several transcatheter treatment options have been developed with the intention to either limit the reverse vena caval backflow secondary to severe TR or to decrease the tricuspid annular dimensions and facilitate the coaptation of the leaflets. Several devices are currently under preclinical and clinical evaluation, targeting different anatomic structures of the right heart, mainly the valve itself (ie, the annulus, the leaflets, and subvalvular apparatus), the right ventricle, and the superior and inferior caval veins (Table 2).¹⁸⁻²⁸

Balloon-expandable caval implants. Due to the large size of the native TA and lack of calcium, devices commonly used to treat aortic stenosis (eg, 29-mm Edwards Sapien XT or Sapien 3 [Edwards Lifesciences]) cannot be implanted into the native TA. However, caval implantations of these devices have been used off label for the treatment of severe TR. A self-expandable large stent (diameter, 26–30 mm; length, 40–80 mm) (eg, Sinus XL [Optimed Medizinische Instrumente GmbH]) is initially implanted in the IVC to make the anchoring of the prosthetic valve feasible. The 29-mm Edwards Sapien XT or Sapien 3 valve (Figure 1) is then deployed inside the stent with the lower part just superior to the confluence of the first hepatic vein.

At least 10 patients have been treated so far for compassionate use. Nine patients received the prosthesis solely in the IVC, while one patient had the device placed in both caval veins. Technical success was obtained in all patients without paravalvular leak, and no complications during the hospitalization were observed. New York Heart Association (NYHA) class and right ventricular function (measured with tricuspid annular plane systolic excursion) improved in nine patients. The 30-day mortality rate was 20% (data presented at Transcatheter Valve Therapies Congress 2015).

TABLE 2. SUMMARY OF INITIAL TRANSCATHETER TREATMENT OF NATIVE TRICUSPID VALVE REGURGITATION

Device	Technique	Ongoing Study	Current Experience	N	Mean Follow-Up Time (mo)	Results	Technical Success
TricValve ^{18,19}	Bicaval valve implantation (CAVI)	–	Clinical	5	7 ± 13	Abolishment of caval regurgitation	• 1 implant failure (required conversion to surgery) • Significant hemodynamic improvement • Relief of HF symptoms • Moderately improved physical capacity
Sinus XL (large, 26–30); Sapien XT (or Sapien 3) (29) ²⁰	Balloon-expandable caval implantation	TRICAVAL (randomized, single center) HOVER (prospective, single center)	Clinical	10	9 ± 11	• Improvement of at least 1 NYHA functional class • Improvement in RV function	90% implanted at the level of the IVC only
Forma repair system ²¹	Coaptation surface	Early feasibility trial ongoing in the United States (NCT02471807)	Clinical	7	5 ± 1	• Improvement in NYHA functional class • Reduction in peripheral edema • Reduction in diuretic dose • Improvement in exercise capacity and quality of life	–
Mitralign device ²²⁻²⁴	Annuloplasty	• Compassionate use • SCOUT (early feasibility) • SCOUT 2 (EU CE Mark study)	Clinical	16, 10	–	• Reduction > 50% in TA diameter and EROA • Significant decrease in RA pressure • Increase in LV stroke volume • Significant improvements in exercise tolerance	–
TriCinch device ²⁵	Annuloplasty	PREVENT (early feasibility)	Clinical	10	6	• Improvements in quality of life • Improvement in NYHA functional class (up to I-II)	–
MitraClip ^{26,27}	Valve plasty	–	Clinical	–	–	Immediate TR reduction	–
Traipta ²⁸	Intrapericardial annuloplasty	–	Animal models	–	–	–	–
Millipede	Ring annuloplasty	–	Preclinical and first in man	–	–	Immediate reduction in annular dimensions and TR	–

Abbreviations: EROA, effective regurgitant orifice area; FU, follow-up; HF, heart failure; IVC, inferior vena cava; NYHA, New York Heart Association; RV, right ventricle; TA, tricuspid annulus.

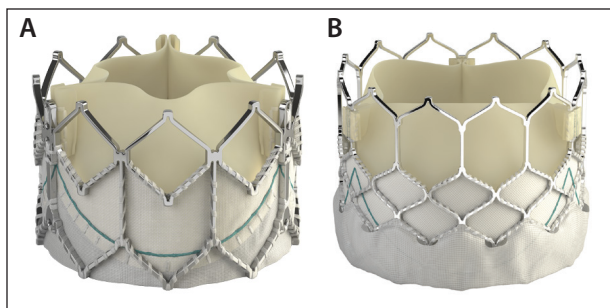


Figure 1. Sapien XT (A) or Sapien 3 (B) can be utilized for balloon-expandable caval implantation.

Bicaval valve implantation with a dedicated self-expandable valve. The goal of superior and IVC valvular prostheses is not to improve valvular function per se, but to decrease the regurgitation of blood into the caval veins, a frequent condition in patients with severe TR, so that blood congestion in the liver and other splanchnic organs is reduced.^{18,29,30}

The Tric Valve device (P&F Products & Features Vertriebs GmbH, in cooperation with Braille Biomedica) is specifically designed for this procedure (Figure 2). The device consists of two self-expandable bioprosthetic valves available in sizes of 28 to 43 mm.

In preclinical studies, the self-expandable bicaval valvular prosthesis was effective in reducing caval backflow and improving cardiac output in short- and mid-term follow-up.^{31,32} Clinical experience began in 2011, and five patients have been treated so far.¹⁸ The device was successfully implanted in four patients; in one patient, the device could not be deployed as intended, and conversion to surgery was required. At a mean clinical follow-up of 7.4 ± 13.2 months, valvular function was excellent, with significant hemodynamic improvement and relief of heart failure symptoms and moderately improved physical capability.^{18,19}

The TriCinch system. The TriCinch system (4Tech Cardio Ltd.) is a percutaneous annuloplasty system designed specifically to correct functional TR (Figure 3). The device consists of an anchoring system (stainless steel corkscrew), a nitinol self-expandable stent (27, 32, 37, or 43 mm), and a Dacron band connecting both. The stainless steel corkscrew is anchored in the anteroposterior portion of the TA through a flexible catheter introduced through femoral venous access guided by fluoroscopy and transesophageal and intracardiac echocardiography. The implantation location is identified using baseline cardiac CT. Once the anchoring system is in place, traction is applied to the system to determine a reduction in the TA diameter and the degree of regur-

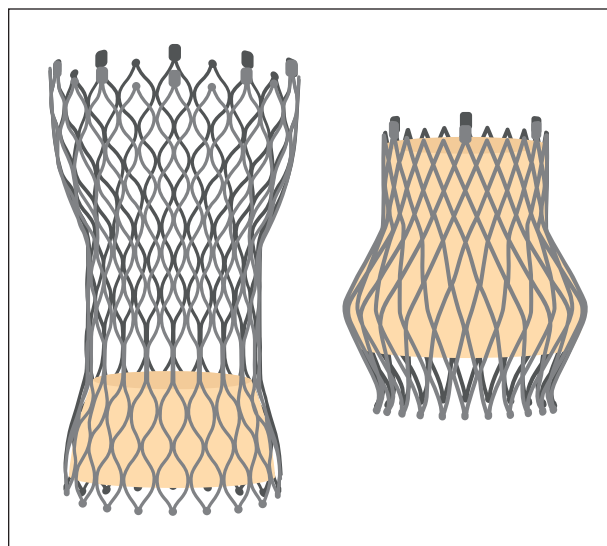


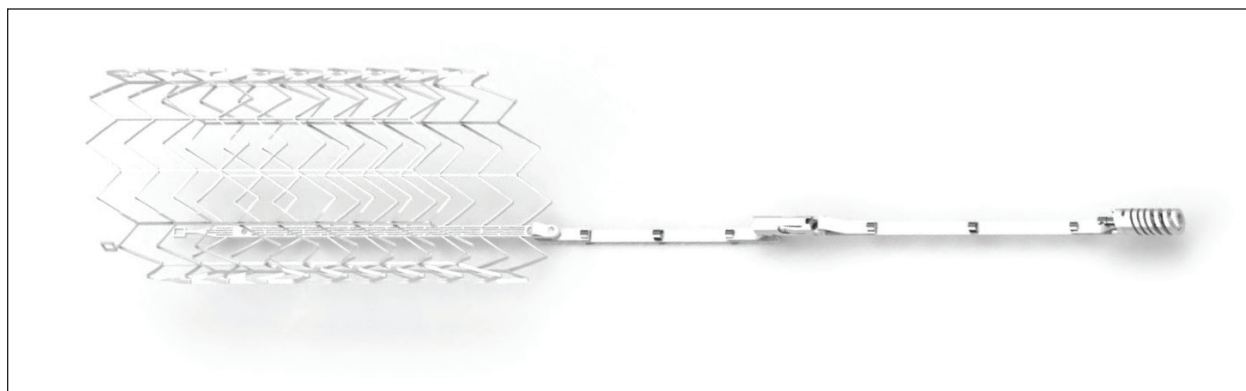
Figure 2. The Tric Valve device.

gitation. The stent is then connected to the anchoring system and released into the IVC to maintain the tension of the system on the TA.

The PREVENT study (NCT02098200), which used the TriCinch system, was designed to evaluate the safety and efficacy (reduction of at least one degree of valvular regurgitation) of the TriCinch system in 24 patients with TR. So far, 10 patients have been enrolled, and three have completed 6-month follow-up. The mean duration of the procedure was 63 ± 10 minutes. After 6 months, the device was stable in three patients. Two patients reported an improved NYHA functional class to I and the other patient to class II. The results of a 6-minute walking test (from 293–336 m compared to baseline) and the Minnesota Living with Heart Failure questionnaire (from 44 to 19) also improved.

The Trialign device. The Trialign device (Mitralign Inc.) (Figure 4), originally designed for percutaneous treatment of functional mitral regurgitation,³³ has been recently used to treat TR. Trialign is an annuloplasty system that reproduces the Kay surgical technique,³⁴ thus converting an incompetent tricuspid valve into a bicuspid valve by the plication of both anterior and posterior TA. Through a transjugular approach and with fluoroscopic and transesophageal echocardiographic guidance, two pledgets are positioned at the level of the annulus in proximity to the anteroposterior and posteroseptal commissure, to plicate the annulus itself and thus reduce its circumference.

The first-in-human procedure was conducted in September 2014.²² The successful procedure determined a 57% reduction in the annular area and consequent



Courtesy of Atritech Cardio Ltd.

Figure 3. The TriCinch system.

reduction in TR and right atrial pressure, as well as an increase in left ventricular stroke volume. The patient tolerated the procedure well and was discharged from the hospital 5 days later with a significant improvement in exercise capacity. Results from a procedure that used a single pair of pledgets performed with Trialalign for TR has confirmed feasibility and safety among 16 compassionate use case patients. A US Food and Drug Administration early feasibility study is underway, and a multicenter European study to obtain CE Mark approval is about to begin enrollment.

The Forma system. The Forma system (Edwards Lifesciences) is a new option for percutaneous treatment of severe TR in patients with severe dilation of the TA and lack of leaflet coaptation (Figure 5). This system includes a spacer (diameter, 12 and 15 mm) placed at the tricuspid orifice so as to constitute a platform for leaflet coaptation. This device is implanted via venous access (subclavian or axillary vein) and is anchored distally and proximally to the apex of the right ventricle.

Preliminary results in seven patients are available; data were presented at the Transcatheter Valve Therapies Congress 2015.²¹ The device was correctly positioned without major complications in all patients, with mild to moderate improvement of the TR. At 30-day follow-up, there were no device-related complications, and improvements in NYHA class and heart failure signs and symptoms were observed.

Transatrial intrapericardial tricuspid annuloplasty. Trans-auricular intra-pericardial tricuspid annuloplasty (TRAIPTA) is a catheter-based repair system (National Institutes of Health) dedicated to the treatment of severe TR secondary to annular dilatation. The system consists of a custom-made memory-shaped delivery device inserted into the atrioventricular groove through

a puncture of the right atrial appendage. The delivery system positions a circumferential suture, which is tightened to achieve the desired degree of TA reduction. The suture is secured and cut, and the access in the pericardial space is closed with an occluder placed in the right atrial appendage. A feasibility study in 16 swine demonstrated the safety and effectiveness of this technology, with a consistent reduction in the TA diameters. No cases of embolization and/or dislocation of the device were reported; the only reported complication was the presence of moderate pericardial effusion without cardiac tamponade.²⁸

Other options in native valve. The MitraClip device (Abbott Vascular) is used widely for the treatment of both organic and functional mitral regurgitation (Figure 6). The use of the MitraClip for the correction of TR is in an experimental phase. The first-in-human implantation was performed in a patient with congenital transposition of the great vessels.³⁵ A recent case series of three patients has documented the feasibility of MitraClip implantation in cases of functional TR.²⁶ MitraClip implantation can be performed through the internal jugular or femoral vein and consists of the grasping of two continuous or opposite leaflets with the rationale of reproducing either a bicuspidalization or a “clover plasty.” The results of the first case series are good, in terms of functional recovery and reduction of TR²⁶; however, considering the numerous challenges of this approach (ie, the three-leaflet configuration of the tricuspid valve, the presence of an extreme dilatation of the TA, the lack of leaflet coaptation, and quality of echocardiographic images that is generally suboptimal), the selection of the candidates needs to be carefully evaluated to obtain both good clinical and echocardiographic results.

The Millipede IRIS (Millipede, Inc.) is an adjustable semi-rigid, complete annuloplasty ring that has been

Courtesy of Mitralign Inc.

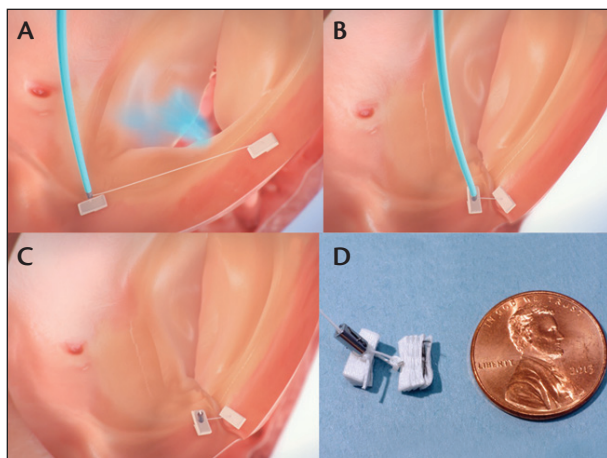
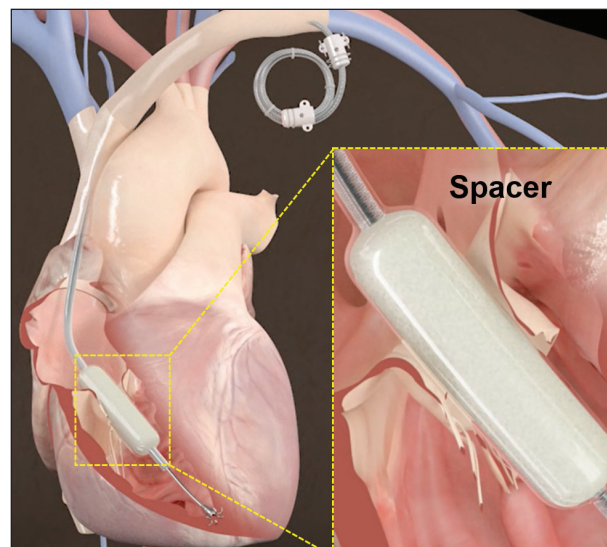


Figure 4. Illustration of the Trialign device showing a pair of pledgets prior to plication (A), pledgets being plicated (B), and final implantation (C). Photograph showing the the pledgets next to a penny to demonstrate scale (D).

used clinically in the mitral and tricuspid positions (Figure 7). Nine surgical patients have been treated with the IRIS ring with an initial temporary placement series, and recently a series of permanent implants reduced the valve diameter by up to 50% and reduced the MR grade to zero in all but one patient (data presented at EuroPCR 2016). The longest follow-up of nearly 6 months with echo and CT data were recently presented at the Transcatheter Valve Therapies and the EuroPCR meetings. These surgical implants have demonstrated the feasibility and efficacy of the annuloplasty ring. Currently, the company is completing development of the transfemoral-transseptal delivery catheter, which has been used in numerous animal studies to deliver the IRIS ring.

Transcatheter tricuspid valve-in-valve implantation for the treatment of dysfunctional surgical bioprosthetic valves. Valve-in-valve (VIV) procedures are an attractive alternative to repeat surgical procedures for the treatment of degenerated bioprostheses in high-risk patients. The presence of a circumferential valvular ring provides a landing zone to anchor a valved stent, thus allowing transcatheter VIV implantation. The treatment of failed tricuspid bioprostheses has been reported in 71 patients using either a Melody transcatheter pulmonary valve (Medtronic) or a Sapien 3 transcatheter heart valve (Edwards Lifesciences). Both transjugular and transfemoral routes were approached. The operative strategy consisted in the preimplantation of a stent in 11 patients, whereas in 22 cases, predilatation was used to make an appropriate sizing. In the remaining cases, the operators preferred a direct valve implanta-



Courtesy of Edwards Lifesciences.

Figure 5. The Forma system.

tion. In 12 cases, postdilatation was used to optimize the final result, generally after the release of the Melody Transcatheter Pulmonary Valve. The echocardiographic and clinical results were noteworthy, with a significant reduction of the transvalvular gradients (pre-VIV mean gradient, 11 ± 4 mm Hg; post-VIV mean gradient, 3.8 ± 2 mm Hg) and the absence of significant perivalvular regurgitation.³⁶

A recently published multicenter registry evaluated the clinical outcome in 156 patients with failed tricuspid bioprostheses. In 94 patients, the failure of the tricuspid valve was managed with the implantation of the Melody transcatheter pulmonary valve, and in the remaining 58 cases, a Sapien 3 transcatheter heart valve was chosen. The rate of procedural complications was low (two device embolizations). At 1-year follow-up, 17 patients had died, and except for one, all deaths were unrelated to the procedure.³⁷ We also recently published our clinical experience with five transcatheter tricuspid VIV procedures with balloon-expandable devices for bioprosthetic failure.³⁸ During 30-day follow-up, all patients reported a significant improvement in their functional status with normal valve function. Additionally, we observed an improvement in renal function (estimated glomerular filtration rate baseline, 62 ± 16.5 mL/min/1.73 m² vs follow-up, 70.2 ± 23.1 mL/min/1.73 m²; $P = .12$) and improved hepatic congestion in bilirubin ($1.47 \pm .08$ mg/dL vs 1.01 ± 0.7 mg/dL; $P = .12$) and alanine aminotransferase (35.8 ± 6.3 U/L vs 29.8 ± 13.6 U/L; $P = .12$).

Tricuspid valve-in-ring implantation. Only four cases of valve implantation in a tricuspid prosthetic ring

Courtesy of Abbott Vascular.

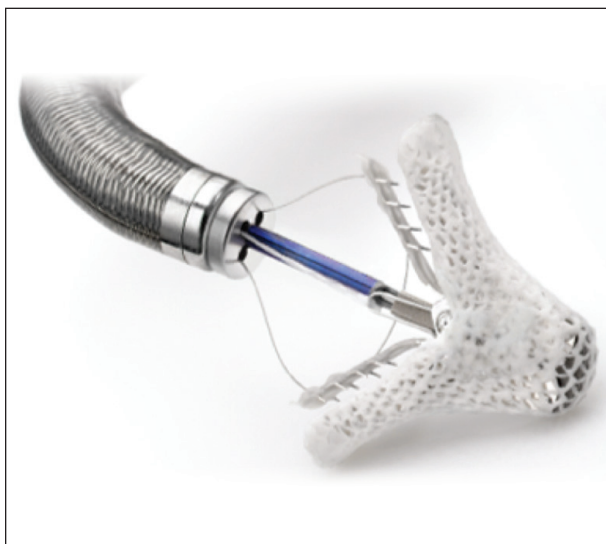


Figure 6. The MitraClip device.

Courtesy of Millipede, Inc.



Figure 7. The Millipede IRIS device.

have been reported.³⁹ Several challenges have emerged in the correction of the failure of tricuspid valve rings:

The exact sizing of the incomplete prosthetic ring is challenging because of the tridimensional shape and presence of an opened portion of ring in correspondence of the septum. The native tricuspid annulus is mostly free from calcification, resulting in a complicated implantation of the valve even if the support of a prosthetic ring is present. Prosthetic rings for the correction of tricuspid annular dilatation can be flexible with the risk of suboptimal sealing of the prosthetic valve.

In the future, more conformable or repositionable valves designed to improve the sealing after valve deployment may help to reduce the residual regurgitation.

CONCLUSION

Functional TR is a frequent condition with a significant impact on functional status and survival. Unfortunately, isolated surgical tricuspid repair/replacement remains infrequent due to the high operative risk, especially in patients who have undergone left-sided cardiac surgery. Thus, development of percutaneous techniques is very appealing as an alternative to surgical treatment. The initial in-human experiences limited to a few high-risk patients demonstrated feasibility and, in some cases, efficacy. Prospective registries with higher numbers of patients and longer follow-up are needed to better evaluate the safety and efficacy of these treatment options. ■

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