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REVIEW

Advancements in transcatheter tricuspid valve repair and replacement: a state-of-the-art review with echocardiographic outcomes

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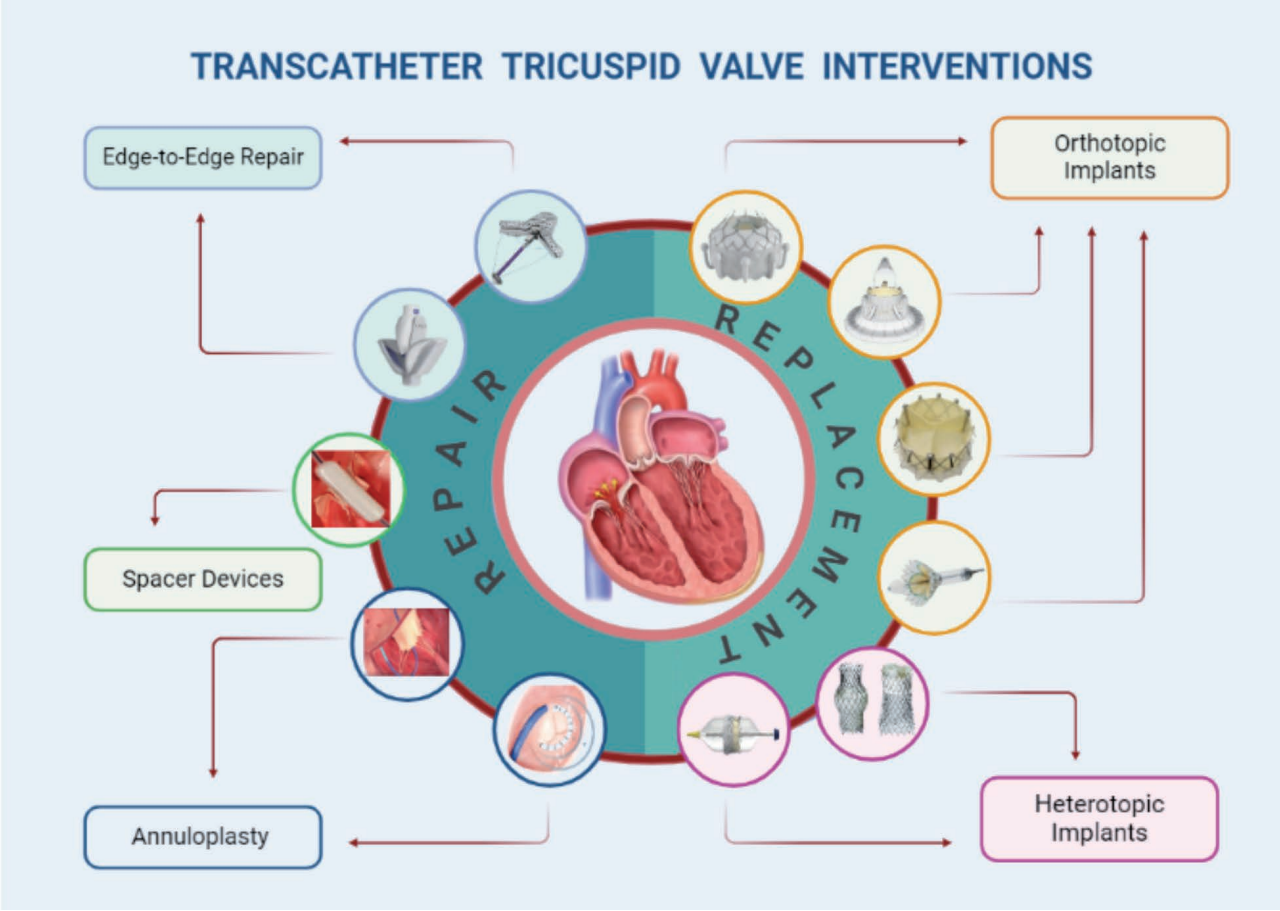
Graphical abstract



Abstract

Tricuspid regurgitation (TR) affects over 1.6 million individuals in the United States, with a one-year mortality rate of 36.1% and a five-year survival below 30%. Despite its prevalence being comparable to mitral regurgitation and aortic stenosis, TR remains understudied and inadequately managed. The underlying causes of TR vary, with primary TR stemming from structural abnormalities of the tricuspid valve, including damage caused by infectious endocarditis, rheumatic heart disease, congenital anomalies, or trauma, while secondary TR arises from right ventricular pressure and volume overload due to conditions such as heart failure (HF), atrial fibrillation, and pulmonary hypertension (PH). As TR progresses, it leads to higher hospitalization rates and imposes a significant healthcare burden, particularly in patients with advanced HF and PH. Medical therapy provides only symptomatic relief, while surgical intervention, carries high in-hospital mortality and complication risks. Given these challenges, transcatheter tricuspid valve interventions (TTVI) have emerged as promising alternatives, offering both transcatheter tricuspid valve repair (TTVr) and replacement (TTVR) strategies. TTVr devices such as TriClip, PASCAL, and Cardioband enhance leaflet coaptation or reduce annular dilation while preserving the native valve, resulting in lower procedural risks and faster recovery. Meanwhile, TTVR devices such as Evoque, TricValve, and LUX-Valve provide a definitive solution for patients with severe annular dilation, large coaptation gaps, or significant leaflet tethering. The growing population of underserved TR patients and the favourable outcomes of transcatheter therapies have accelerated advancements in device development and expanded treatment options. This review explores the latest advancements in TTVr and TVVR strategies, highlighting their clinical significance and echocardiographic outcomes based on recent data.

Key words: tricuspid regurgitation; tricuspid valve; transcatheter tricuspid valve interventions.

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Introduction

Tricuspid regurgitation (TR) is one of the most common valve conditions, affecting over 1.6 million people in the United States[1] with a staggering one-year mortality rate of 36.1%.[2] Despite TR being as prevalent as mitral regurgitation and aortic stenosis,[3-4] the tricuspid valve has historically received less attention, earning it the designation of the 'forgotten valve" and leading to its subpar management.[5] TR is classified as either primary or secondary, with primary TR resulting from structural damage to the tricuspid valve or annulus due to conditions such as infectious endocarditis, rheumatic heart disease, congenital anomalies, or trauma. In contrast, functional or secondary TR is caused by increased right ventricular pressure and volume, ultimately leading to the backflow of blood through the tricuspid valve. Common causes include heart failure (HF), atrial fibrillation, and pulmonary hypertension (PH).[6-9] With a five-year survival rate of less than 30% and a high hospitalization rate due to PH and HF, TR continues to be a heavy burden on the healthcare system.[7]

Historically, medical therapy was the primary approach for TR management, offering only symptomatic relief without addressing the underlying pathology. As a result, surgical intervention became the standard of care. However, its high in-hospital mortality and complication rates[10] highlighted the need for safer and more effective alternatives. In response, advances in transcatheter technology have led to the development of minimally invasive transcatheter tricuspid valve interventions (TTVI), offering both repair and replacement options. The high number of underserved patients and early evidence of safe and successful outcomes following TTVI has led to rapid growth in the production and implication of these devices.[11] Hence, in this review, we explore the latest transcatheter tricuspid valve repair and replacement strategies, with a particular focus on clinical and echocardiographic outcomes based on emerging evidence.

Pathophysiology of tricuspid regurgitation

Suspended between the right atrium and right ventricle, the tricuspid valve apparatus consists of four key components: the anterior, posterior, and septal valve leaflets; the tricuspid valve annulus; the chordae tendineae; and the papillary muscles.[12] TR can result from primary structural defects or secondary anomalies caused by myocardial dysfunction or dilatation.[13] Persistent high pressures from PH and HF lead to volume overload, cardiac remodeling, and right ventricular dilation.[14] As the right ventricle enlarges, the tricuspid annulus dilates, preventing proper leaflet coaptation and allowing regurgitant blood flow. This ongoing volume overload further stresses the right ventricle, creating a self-perpetuating cycle that exacerbates TR.[15-16]

Repair *versus* replacement

The reduced procedural risk and improved patient outcomes have led to a dramatic rise in the implementation of tran-

scatheter tricuspid devices.[17] In the current landscape, there are two options: transcatheter tricuspid valve repair (TTVr) and transcatheter tricuspid valve replacement (TTVR). TTVr approaches mainly target preserving the natural valve anatomy and minimizing TR through improved leaflet coaptation or tricuspid annular reduction. These TTVr options, such as TriClip, PASCAL, and Cardioband, typically require a lesser degree of valve manipulation, resulting in fewer procedural hazards and shorter recovery periods.[18-19] On the other hand, TTVR devices such as the Evoque, TricValve, and LUX-Valve completely replace the native tricuspid valve with a prosthetic unit. Since TTVR interventions offer a more precise solution to TR by removing the regurgitant flow permanently, patients with complex valvular anatomy, such as significant coaptation gaps, substantial annular dilation, or severely tethered septal leaflets, can potentially benefit from them.[15] However, the ultimate decision between repair and replacement is based on patient-specific factors such as the degree of tricuspid valve impairment, anatomical adequacy, concurrent medical conditions, and long-term management challenges.

Transthoracic echocardiography (TTE) is considered the gold standard imaging for evaluation and grading of the severity of TR.[20] For patients with an inadequate transthoracic acoustic window, a 3-dimensional (3D) transesophageal echocardiography (TEE) is typically adopted.[21] Additional imaging modalities, such as cardiac magnetic resonance (CMR) or cardiac computed tomography (CCT), are advised when echocardiographic quality is inadequate or the severity indicators are inconsistent.[22] For grading the severity of TR, an advanced color flow doppler is routinely used.[23] However, recent guidelines suggest that newer techniques like measuring vena contracta (VC) and proximal isovelocity surface area (PISA) are the most effective methods to quantify TR severity, with systolic hepatic flow reversal being the strongest and specific additional parameter.[24]

Transcatheter tricuspid valve interventions

TTVI for TR necessitates careful inspection of valve anatomy, TR mechanism, physiologic variables such as right heart size and function using imaging, and the patient's clinical status. These factors drive the therapeutic plan of action and the primary choice between TTVr and TTVR (Tables 1 and 2).

Transcatheter tricuspid valve repair techniques

Tricuspid edge-to-edge repair

Edge-to-edge repair is a transcatheter approach that involves approximation of the free edges of the valve leaflets to improve coaptation defect and reduce the regurgitant orifice (Figure 1).

Table 1. Clinical and echocardiographic outcomes for major transcatheter tricuspid valve repair (TTVr) devices.

	TriClip™ and MitraClip™	PASCAL	Cardioband	TriAlign	TriCinch	Milipede IRIS	FORMA
Clinical outcomes							
Procedural success rate	>90%	>85%	>90%	>80%	>80%	>90%	>90%
Improvements to NYHA Functional Class I/II	>75% of patients	>85% of patients	>80% of patients	>80% of patients	Not Published	>80% of patients	>80% of patients
Complication and mortality rates	0% procedural deaths, 0.5% all-cause mortality, 2% MAEs at 30 days	10% all-cause mortality, 4.8% CVS deaths at 1 year	1.6% all-cause mortality, 19% MAEs at 30 days at 30 days	0% procedural deaths, 20% annular detachment	0% mortality, 23% MAEs at 30 days	0% mortality at 30 days	0% mortality at 30 days, 23% mortality at 3 years
Key study/trial	TRILUMINATE Trial,[22] bRIGHT study[23]	TRI-REPAIR,[31] Tri-Band Study[32]	CLASP TR-Trial[28]	SCOUT Trial[34]	PREVENT Trial[36]	-	EarlyFeasibilty Study,[44] SPACER Trial
Echocardiographic outcomes (compared to baseline)							
EROA	>30% reduction	>55% reduction	>55% reduction	>25% reduction	>45% reduction		>45% reduction
PISA radius	>20% reduction	-	-	>35% reduction	-		>45% reduction
VC width	>50% reduction	>60% reduction	>35% reduction	>30% reduction	-		>30% reduction
Regurgitant volume	>55% reduction	>55% reduction	-	8% reduction	-		-
RVEDD	5-10% reduction	>10% reduction	>15% reduction	-	-		-
Tricuspid annular diameter	<10% reduction	>10% reduction	>15% reduction	5% reduction	7% reduction	>35% reduction	>5% reduction
Right atrial volume	7-10% reduction	>10% reduction	>20% reduction	-	-		>15% reduction
Tricuspid annular area	-	-	-	8% reduction	-		-
IVC diameter	-	>15% reduction	>10% reduction	-	-		-

MAEs, major adverse events; CVS, cardiovascular; NYHA, New York Heart Association; EROA, effective regurgitant orifice area; PISA, proximal isovelocity surface area; VC, vena contracta; IVC, inferior vena cave; RVEDD, right ventricular end-diastolic diameter.

Table 2. Clinical and echocardiographic outcomes for major transcatheter tricuspid valve replacement (TTVR) devices.

	EVOQUE	LUX-valve	NaviGate	Sapien*	TricValve
Procedural success rate	>90%	100%	>90%	100%	>90%
NYHA functional class I/II improvements	>90% of patients	>75% of patients	>70% of patients	>80% of patients	>75% of patients
Complication and mortality rates	26% MAEs, 3% all-cause mortality at 30 days	0% mortality, 7% MAEs at 1 year	10% all-cause mortality, 13% MAEs	0% procedural deaths, 0% MAEs	8.5% all-cause mortality at 6 months
Key study/trial	TRISCEND study[47]	-	-	TRICAVAL trial (ended prematurely)[65]	TRICUS EURO study[68]
TAPSE	>10% reduction	Improved by >25%	>10% reduction	Improved by 15-25%	5% reduction
IVC diameter	>20% reduction	-	-	-	-
VC width	-	-	>75% reduction	-	<5% reduction
RVEDD/ RVEDA	>25% reduction	>10% reduction	-	-	0% reduction
RAV	>10% reduction	>30% reduction	-	-	-

*Data from case report/case series; MAEs, major adverse events; CVS, cardiovascular; NYHA, New York Heart Association; EROA, effective regurgitant orifice area; PISA, proximal isovelocity surface area; VC, vena contracta; IVC, inferior vena cave; TAPSE, tricuspid annular plane systolic excursion; RVEDD, right ventricular end-diastolic diameter.

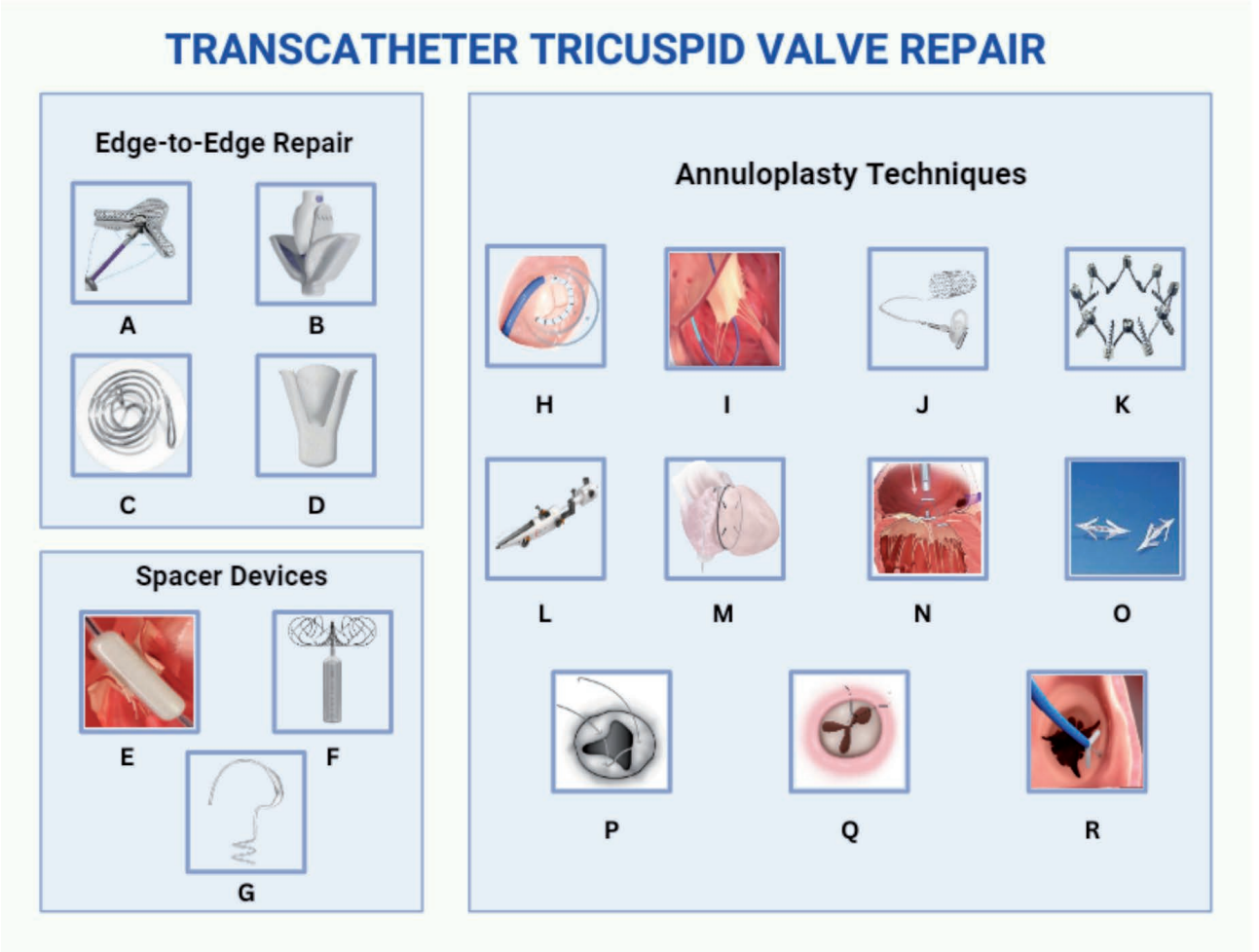

Figure 1. Current and emerging transcatheter tricuspid valve repair (TTVr) options. A) TriClipTM; B) PASCAL system; C) Mistral; D) DragonFlyTM; E) FORMA system; F) TriPair; G) Pivot-TR; H) Cardioband; I) TriAlign; J) TriCinchTM; K) Millipede IRIS;(L) DaVingi™ TR system; M) TRAIPTA system; N) PASTA system; O) MIA system; P) TASTI technique; Q) StarTric system; R) K-Clip system.

MitraClipi™ and TriClipi™ systems

The MitraClip™ and TriClip™ systems (Abbott Vascular, USA) are currently the most widely used tricuspid edge-to-edge repair techniques. Similar in operation, these devices are cobalt-chromium implants with two arms, with the TriClip™ having two additional knobs for catheter steering to optimize device trajectory to the tricuspid valve and efficient leaflet grabbing.[25]

Clinical outcomes: significant data on optimal outcomes with the use of these devices for TR has been reported. The TRILUMINATE trial[26-27] enrolled 85 patients and found that TriClip™ reduced the severity of TR by at least one grade in 86% of the patients at 30 days and two years after intervention. Additionally, the hospitalization rate decreased by 49%, and significant improvements were seen in 6-minute walking distance (6MWD), New York Heart Association (NYHA) functional class, and Kansas City Cardiomyopathy Questionnaire (KCCQ) scores. Similarly, results at one year from the bRIGHT (An Observational Real-World Study Evaluating Severe Tricuspid Regurgitation Patients Treated with the Abbott TriClip Device) study[28] reported a 99% procedural success rate for the TriClip™ system, a reduction in TR severity for 81% of the patients, NYHA class improvement for 75% of the patients, and mortality rates as low as 1%. Another study including 64 patients found that MitraClip™ reduced TR severity in 91% of the patients with significantly improved NYHA class and 6MWD.[29] The TriValve Registry reports procedural success in >80% of the enrolled patients and effective reduction in TR severity with MitraClip™ intervention.[30] The 12-month follow-up revealed a 91% survival rates in patients with atrial severe TR.

Echocardiographic outcomes: post-procedural echocardiographic findings support the efficacy of both MitraClip™ and TriClip™ systems in reducing TR defining parameters. The bRIGHT study[28] showed significant reductions in the effective regurgitation orifice area (EROA) (0.80±0.51 to 0.42±0.38 cm^2; $p<0.0001$), regurgitant jet area (10.41±5.34 to 6.07±4.74 cm^2; $p<0.0001$), PISA radius (0.82±0.22 to 0.56±0.34 cm; $p<0.0001$), and VC width (0.85±0.36 to 0.50±0.36 cm; $p<0.0001$). Similarly, the two-year follow-up of the TRILUMINATE trial[27] reports reduced VC width (1.61±0.54 to 0.71±0.32 cm; $p<0.0001$), EROA (0.66±0.22 to 0.44±0.29 cm^2; $p=0.0116$), regurgitant volume (52.54±14.06 to 33.51±16.07 mL/beat; $p=0.0003$), and PISA radius (0.92±0.16 to 0.72±0.18 cm; p=0.0009). Moreover, post-procedure trends in the enhanced remodeling of the right heart were observed with these interventions. Decreased right ventricle end diastolic diameter (RVEDD) (4.63±0.92 to 4.28±0.86 cm and 5.28±0.07 to 4.77±0.10 cm), decreased tricuspid annular diameter (4.54±0.76 to 4.27±0.73 cm and 4.33±0.59 to 4.06±0.5 cm), and decreased RAV (151.66±70.46 to 136.25±62.35 mL and 128.04±53.88 to 119.79±56.22 mL) were reported, indicating enhanced cardiac function.[26-28]

The economic concerns with the use of advanced management options are very common. However, in a cost-effectiveness analysis,[31] the 5-year survival rate was 49.91% for the medical treatment and 57.64% for the TriClip™ intervention. TriClip™ was deemed cost-effective compared to medical treatment, with patients gaining an average of 1.64 years of life.

PASCAL system

The PASCAL system (Edwards Lifesciences, USA) consists of a steerable catheter, an implant catheter, a guide sheath, a stabilizer, and adjacent paddles and clasps that aid the attachment on the native valve leaflets to reduce regurgitation.[32]

Clinical outcomes: CLASP TR (Edwards PASCAL Transcatheter Valve repair System in Tricuspid Regurgitation)[33] is a major study involving 65 patients, providing insights into the efficacy and safety of the PASCAL system. With a procedural success rate of 88%, one-year follow-up results showed a significant 70% reduction in TR severity to moderate or less ($p<0.001$). Furthermore, improvements in NYHA functional class were seen in over 88% of the patients, along with significant increases in 6MWD and KCCQ scores. These results are consistent with the first-in-human experience study[34] of the PASCAL system, which enrolled 28 patients with severe TR. With a procedural success rate of 86% and a mortality rate of 7%, the PASCAL system demonstrated improvements in the NYHA class and 6MWD in all patients.

Echocardiographic outcomes: post-interventional echocardiographic findings demonstrate favourable outcomes with the PASCAL system. The CLASP TR study[33] reported significant reductions in EROA (0.7±0.3 to 0.3±0.1 cm^2; $p<0.001$), PISA regurgitant volume (53.3±16.7 to 22.6±11.0 mL; $p<0.001$), VC width (1.4±0.4 to 0.5±0.2 cm; $p<0.001$), and regurgitant jet area (15.1±5.0 to 6.9±3.6 cm^2; $p<0.001$). Additionally, right heart remodeling and function improved significantly, as evidenced by TEE findings, which showed a reduction in tricuspid annular diameter (4.5±0.8 to 4.0±0.6 cm and 47.4±7.3 to 40.3±7.1 mm), RVEDD (4.0±0.9 to 3.5±0.7 cm), and RAV (148.9±81.7 to 130.6±63.9 mL).[33-34]

The PASCAL system has several distinct advantages over other edge-to-edge repair systems. For instance, the presence of a central spacer, a broader area, and independently operating clasps allow it to better dispense the forces exerted on the tricuspid valve leaflets, maximize leaflet attachment to the device, and thus cover larger coaptation gaps.[34]

Annuloplasty devices

Annuloplasty devices for transcatheter tricuspid repair work by replicating the surgical principles of annuloplasty to reduce, reshape, and resize the dilated tricuspid valve annulus, resulting in improved leaflet coaptation and reduced TR (Figure 1).

Cardioband repair system

The Cardioband tricuspid repair system (Edwards Lifesciences, USA) is a type of ring annuloplasty device that is Conformité Européene (CE) mark approved. It consists of an adjustable suture less ring paired with a polyester sleeve that, when deployed, constricts the dilated annulus and reduces its septolateral diameter.[34]

Clinical outcomes: the TRI-REPAIR study[35-36] showed that at two years of follow-up, the Cardioband system helped more than 80% of patients achieve NYHA Class I-II improvement with a technical success rate of 100%. Additionally, with a two-year survival rate of 73%, significant improvements in the 6MWD and KCCQ scores were reported. Similarly, the TriBand study,[37] incorporating data from 60 patients, reported a procedural success rate of 83.9%, with 74% of patients achieving NYHA class I-II improvement and an overall KCCQ score improvement of 17 points at 30 days. The study also observed an all-cause mortality rate of 1.6% and a composite major adverse event (MAE) rate of 19%, with severe bleeding being the most common complication.

Echocardiographic outcomes: post-procedure echocardiographic findings with the Cardioband system demonstrate a reduction in TR severity and improvements in right heart remodeling and function. Significant reductions were observed in PISA EROA (0.78±0.49 to 0.34±0.23 cm^2; p=0.004), mean VC width (1.23±0.4 to 0.79±0.51 cm; p=0.004), and IVC diameter (2.7±0.6 to 2.3±0.7 cm; p=0.02).[34-35] Additionally, tricuspid valve repair with the Cardioband system led to significant reductions in RVEDD (3.8±0.6 to 3.2±0.6 cm and 4.0±0.8 to 3.6±0.6 cm), RAV (168.8±69.3 to 140.0±65.8 mL), and tricuspid annular diameter (41.9±4.6 to 35.2±4.6 mm and 45.5±4.5 to 36.1±5.0 mm).[35-37]

TriAlign repair system

The Trialign system (Mitralign Inc., USA) is a transcatheter suture-based annuloplasty device that is based on the modified Kay procedure and results in plication of the posterior tricuspid leaflet.[38] The TriAlign repair involves the deployment of a pair of polyester pledgets across the tricuspid annulus, secured by a suture to obliterate the posterior tricuspid leaflet.

Clinical outcomes: The SCOUT trial[39] presents data from 15 patients to assess the early feasibility and safety of the TriAlign system for the treatment of TR. The procedural success rate was 80%, with all enrolled patients demonstrating an improvement in their NYHA functional class (≥1 class, p=0.001), Minnesota living with heart failure questionnaire (MLHFQ) (47.4±17.6 to 20.9±14.8; p<0.001), and 6MWD (245.2±110.1 to 298.0±107.6 m; p=0.008). The findings from the TriValve Registry[30] are in accordance with these results, indicating a 69% procedural success rate and zero deaths at 30 days in the 18 patients who underwent treatment with the TriAlign system.

Echocardiographic outcomes: the TTE findings from the SCOUT trial[39] offer valuable insights, demonstrating notable improvements in TR severity and annular diameter. It is noteworthy that there was significant decrease in the mean VC diameter (1.3±0.4 to 1.0±0.3 cm; p=0.02), EROA by PISA (0.51±0.18 to 0.32±0.18 cm^2; p=0.02), and EROA with quantitative Doppler (0.85±0.22 to 0.63±0.29 cm^2; p=0.04). Furthermore, there was a marked reduction in both the tricuspid annular diameter (4.0±0.5 to 3.8±0.6 cm, p=0.03) and the tricuspid annular area (12.3±3.1 to 11.3±2.7 cm^2; p=0.01), which is indicative of a significant reduction in the severity of TR.

TriCinch system

The TriCinch™ system (4Tech Cardio Ltd., Ireland) is another annuloplasty technique derived from the Kay bicuspidization procedure, designed to serve as a TTVr device. The device is composed of a corkscrew-type implant and a self-expanding metallic stent that work by cinching at the anteroseptal commissure to decrease the septolateral diameter of the tricuspid valve annulus, hence reducing TR.[40]

Clinical outcomes: the clinical data for the TriCinch™ system is limited. A first-in-human feasibility study (PREVENT),[41] which enrolled a cohort of 24 subjects, was conducted to assess the safety and efficacy of this device. The results of this study demonstrated a procedural success rate of 85%. Similarly, the Trivalve Registry[30] also reports data for 14 patients who were treated with the TriCinch™ system for severe TR and demonstrated a procedural success rate of 62.5% and no deaths within 30 days. Additionally, a number of individual case reports[42-43] have documented the successful reduction in severity of TR with the TriCinchTM system, including one case where double device implantation was performed in a single procedure.[44-45]

Echocardiographic outcomes: in one of the documented cases, post-procedural echocardiography revealed a substantial reduction in TR severity and a 50% decrease in EROA (from 2.03 cm^2 to 1.07 cm^2).[42] In line with these findings, another reported case showed a notable decrease in the septolateral dimension of the tricuspid annulus (from 41 mm to 38 mm) when treated with the TriCinch™ system.[43]

Millipede IRIS ring system

The Millipede IRIS ring annuloplasty system (Boston Scientific, USA) is a semi-rigid ring comprising helical stainless-steel anchors that are capable of anchoring directly into the tricuspid annulus and tensioning sliders to facilitate the reduction of the annulus to the desired diameter.[43] Although the Millipede IRIS system has been utilized for the treatment of mitral regurgitation, it is relatively novel in the context of TTVr, consequently limiting the available clinical data. The IRIS has some notable advantages. Primarily, the ring can be repositioned and adjusted prior to final deployment, ensuring a safe approach. Moreover, the ring maintains the native anatomy of the tricuspid valve, keeping the door open for potential future procedures like transcatheter edge-to-edge repair.

Clinical and echocardiographic outcomes: a case series presented the post-interventional TTE results of two patients having symptomatic mitral regurgitation with associated tricuspid annular dilation and functional TR.[46] The concomitant use of Millipede IRIS ring systems for the mitral and tricuspid valves resulted in a significant reduction of 36.6% in the tricuspid annular diameter (48.1 mm to 30.5 mm) and a notable improvement in TR grade (4+ at baseline to 0 at 30 days) in the first patient. The second patient exhibited a 35.7% reduction in tricuspid annular diameter (47.3 mm to 30.4 mm) and a notable decrease in TR grade from 3+ at baseline to 0 at 30 days.

Spacer devices

Spacers for TTVr are innovative devices designed to reduce TR by bridging the space between the tricuspid valve leaflets, thus improving leaflet coaptation and regurgitant flow. FORMA system is an emerging spacer device with increasing popularity (Figure 1).

FORMA system

The FORMA system (Edwards Lifesciences, USA) comprises of a foam-filled, inflatable polymer balloon that acts as a space-filling device. The spacer is placed inside the tricuspid valve over a rail that is anchored to the right ventricular myocardium and ultimately expands passively, serving as a surface for leaflet coaptation and reducing EROA.[47]

Clinical outcomes: the early feasibility study[48] for the FORMA system evaluated 29 patients and showed a procedural success rate of 93%. The study reported a 50% improvement in the NYHA functional class, along with notable increases in the 6MWD and KCCQ scores at 30 days. Another study presented the results of a long-term follow-up over a period of three years as part of the first-in-human experience[49] with the FORMA system. With a procedural success rate of 89%, the study revealed NYHA class improvement in 93% of the patients, along with a significant increase in KCCQ score and 6MWD. The mortality rates after the implantation of the FORMA system were considerably low in both studies (0% at 30 days and 23% at 3 years, respectively).[48-49] These results underscore the importance of this spacer device in reducing TR.

Echocardiographic outcomes: post-intervention echocardiographic results from the early feasibility study[48] showed significant reductions in VC width (1.6±0.5 to 1.1±0.4 cm; p<0.001) and EROA (1.1±0.6 to 0.6±0.4 cm^2; p 0.001), with a non-significant reduction in the tricuspid annular diameter (4.6±0.5 to 4.3±0.5 cm; p=0.09). The long-term results from the first-in-human experience[49] found a significant reduction in VC width at 24 to 36-month follow-up (11.8 to 8.4 mm; p=0.005), with no significant changes in EROA (0.92 to 0.77 cm^2; p=0.51). A trend toward a decrease in tricuspid annulus size (46 to 43 mm; p=0.090) and RAV (165 to 139 mL; p=0.908) was observed, underscoring the FORMA system's potential role in right heart remodeling and TR severity reduction.

Transcatheter tricuspid valve replacement techniques

Orthotopic tricuspid valve replacement

Transcatheter tricuspid valve orthotopic replacement devices are designed to replace the tricuspid valve in its natural anatomical position, within the tricuspid annulus. These devices serve to directly replace the patient's native tricuspid valve, offering a new valve structure that controls blood flow between the right atrium and ventricle (Figure 2).

EVOQUE system

The EVOQUE tricuspid valve replacement system (Edwards Lifescience, USA) is currently the largest available orthotopic replacement valve (52 mm). The valve is equipped with a dedicated delivery system and comprises a nitinol frame with a rileaflet structure manufactured from bovine, along with nine anchors and a fabric skirt.[50]

Clinical outcomes: the one-year outcomes of the first-in-human multicentre experience[51] with the EVOQUE system, which enrolled 27 patients, revealed a significant reduction in the severity of TR, with 96% of patients achieving a TR grade of less than 2+. The all-cause mortality was only 7%, and there was a significant increase in the number of patients classified as NYHA class I/II, rising from 11% at baseline to a substantial 70% at one year (p<0.001). The TRISCEND study[52] represents the largest investigation conducted on the EVOQUE system for TR, including 172 patients. The findings showed a procedural success rate of 93%, a cardiac mortality rate of 9.4%, and that 93.3% of patients were in NYHA class I or II at the one-year follow-up, in contrast to 25.8% at the baseline (p<0.001). Additionally, significant improvements in the KCCQ score and 6MWD were also observed.

Echocardiographic outcomes: the TRISCEND study[52] demonstrated favorable post-procedure TTE outcomes at one year. Significant reductions were observed in the RVEDD (41.4±8.8 to 35.0±7.4 mm; p<0.001), IVC diameter (−7.2±5.9 mm, p<0.001), and right atrial pressure (RAP) (12.0±4.8 to 8.7±4.7 mmHg, p<0.001). Moreover, a considerable decline in the incidence of hepatic vein flow reversal was observed (p<0.001), which substantiates the efficacy of the EVOQUE system in reducing TR severity. The results from the first-in-human experience study[51] showed significant reduction in RVEDD (40.0±7.4 to 33.3±6.9 mm; p=0.005) and the IVC diameter compared with the baseline measurement (27.7±5.0 to 17.5±4.0 mm; p<0.001), reflecting effective right heart remodeling after the implantation of the EVOQUE system.

The TRISCEND II pivotal trial[53] is a randomized controlled trial that is currently underway and intends to compare the safety and efficacy of the EVOQUE system with that of medical therapy. This will be the pioneer randomized controlled trial of a TTVR system in comparison with medical therapy, evaluating various outcomes at 30-days and 6-months follow-up.

LUX-Valve system

The LUX-Valve system (Jenscare Biotechnology, China) is another orthotopic self-expanding tissue valve composed of bovine trileaflets and a nitinol stent frame. With a steerable delivery system, it has a pioneered interventricular anchor for optimal tricuspid valve fixation, making it a radial force-independent valve to hold its position.[54]

Clinical outcomes: a single-center study[55] investigating the efficacy and safety of the LUX-Valve for tricuspid regurgitation in

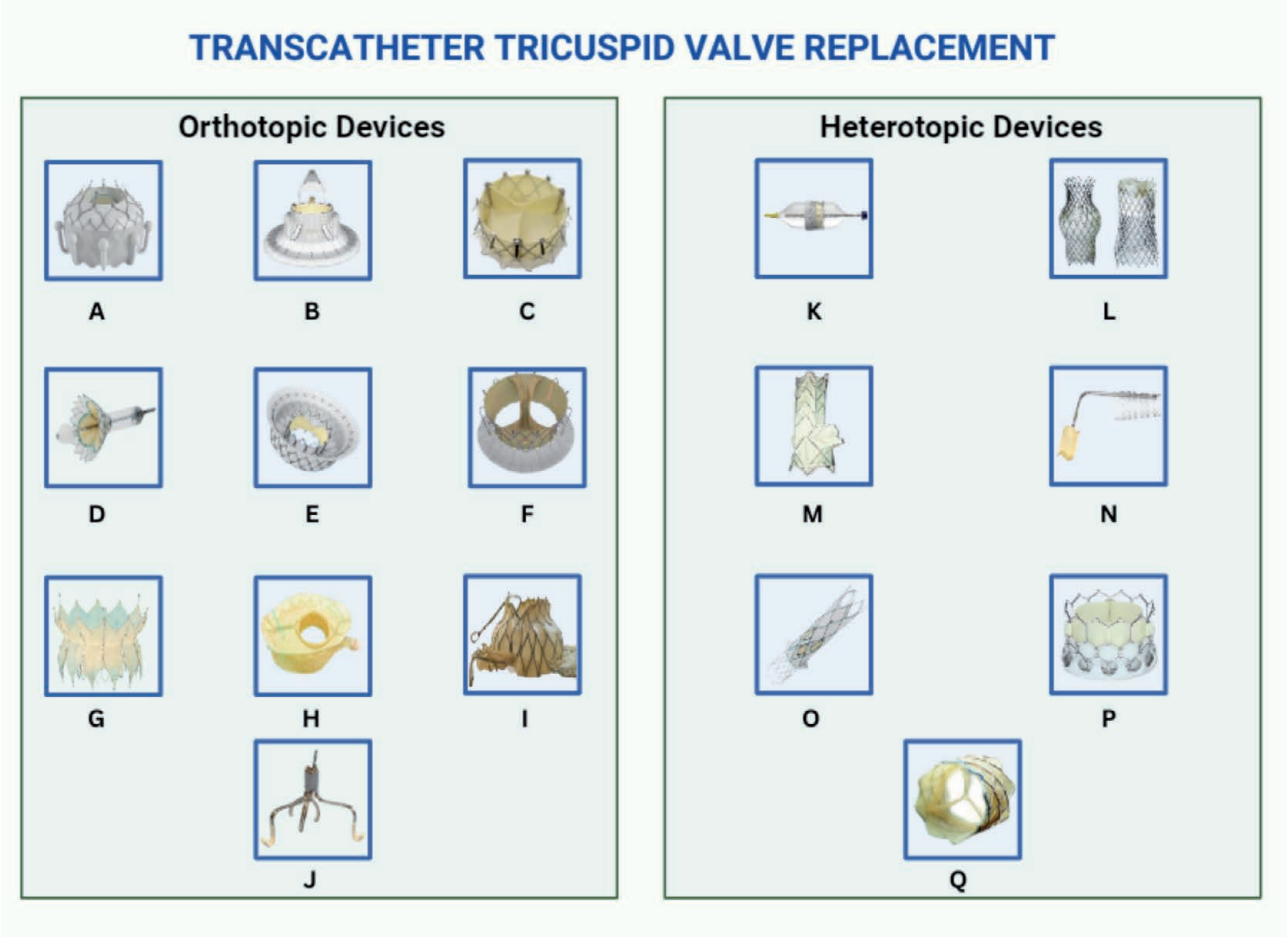

Figure 2. Current and emerging transcatheter tricuspid valve replacement (TTVR) options. A) EVOQUE; B) LUX-Valve; C) NaviGate; D) Cardiovalve; E) INTREPID; F) TriSol; G) TriCares; H) VDyne system; I) Laplace; J) TriFlo; K) Sapien XT; L) TricValve; M) TriCento; N) CroiValve DUO system; O) Trillium; P) MyvalTM; Q) Melody.

15 patients demonstrated a mortality rate of 0% at one-year follow-up. The procedural success rate was 100%, with a significantly higher proportion of patients in NYHA functional class II at the follow-up assessment compared to the baseline (11/14 *vs* 0/15; $p<0.001$). Additionally, there were notable improvements in the 6MWD ($p<0.001$) and KCCQ scores ($p<0.001$). Similarly, another study[56] evaluating 10 patients revealed a procedural success rate of 100% with no mortality and improvement for all the patients in the NYHA functional class at one-year outcomes.

Echocardiographic outcomes: the post-intervention echocardiographic findings at one year by Mao *et al.*[55] show a substantial decrease in the TR severity with the LUX-Valve implantation. Significant reductions were observed in the RVEDD (55.3 to 48.9 mm; $p<0.001$), RAV (188 to 131.5 mL; $p<0.001$), and peak retrograde systolic transtricuspid gradient (18.5 to 5.5 mmH; $p<0.001$). Moreover, significant improvement was recorded in the tricuspid annular plane systolic excursion (TAPSE) (13.0 to 16.3 mm; $p<0.001$), indicating enhanced right ventricular function. These findings are consistent with those of the study by Zhang *et al.*,[56] who reported a significant decrease in the RAP (19.0 to 12.0 mmHg; P=0.01) after implantation of the LUX-Valve.

NaviGate system

The NaviGate valve (NaviGate Cardiac Structures, USA) is a self-expanding tricuspid valve comprising a xenogenic pericardial trileaflet structure encased within a cone-shaped nitinol stent and multiple annular winglets, which serve to secure the valve within the tricuspid annulus.[57]

Clinical outcomes: the early multinational experience study[58] evaluated the feasibility and safety of the NaviGate valve for treating TR in 30 patients. The study demonstrated a technical success rate of 87%. Additionally, the 30-day TR severity was significantly reduced in comparison to the baseline ($p<0.0001$), with 81% of the patients, exhibiting reductions of ≥2 grades. Moreover, all the patients achieved a noticeable improvement

in NYHA functional class at 30 days and discharge (p<0.0005).
Echocardiographic outcomes: the post-procedure echocardiographic findings from the multinational experience study[58] showed a significant reduction in the minimum, maximum, and mean VC width respectively (1.2 to 0 cm; p=0.01, 1.6 to 0.36 cm; p=0.01, 1.37 to 0.32 cm; p=0.01). No notable changes were identified in other echocardiographic parameters, warranting further investigation in this area.

Cardiovalve system

The Cardiovalve system (Cardiovalve Ltd., Israel) is an orthotopic transcatheter mitral and tricuspid valve replacement option that consists of a steerable catheter and three bovine pericardium leaflets with a self-expanding nitinol frame that offers the required radial strength.[59]
Clinical outcomes: the ongoing TARGET trial (NCT05486832)[60] has reported early data for compassionate use in 30 patients.[61] With a mortality rate of 6%, around 92% of the patients were able to achieve improvements in TR severity grade. Additionally, multiple case reports have reported favorable clinical outcomes for the Cardiovalve system for treating TR.[62-64]
Echocardiographic outcomes: currently, no post-interventional echocardiographic outcomes with the Cardiovalve system have been reported.

Intrepid system

The INTREPID system (Medtronic Inc., USA) is a dual-stent, bovine pericardial valve that does not require leaflet capture for anchoring. Initially developed for the mitral valve, the INTREPID valve has a dedicated delivery system and multidirectional steering qualities that facilitate accessing a wide range of anatomies.[65]
Clinical and echocardiographic outcomes: as a realtively novel TTVR device, the INTREPID system has yet to be extensively studied, resulting in limited availability of outcome data. A first-in-human case series of three patients[66] was published, which revealed the successful deployment of the INTREPID system and favorable procedural success. An early feasibility trial (NCT04433065) of the INTREPID system for TR is currently underway.

Heterotopic replacement systems

Transcatheter tricuspid valve heterotopic replacement devices are implanted in a location other than the native tricuspid valve annulus, typically within the IVC or superior vena cava (SVC). These devices function by forming a functional barrier that inhibits the retrograde flow of blood, consequently alleviating the symptoms associated with TR.

Sapien system

The Sapien valve system (Edwards Lifescience, USA) is a well-known device with an FDA-approved indication for severe aortic stenosis. Additionally, it is currently being explored for the treatment of severe TR. It has a bovine pericardial trileaflet attached to a balloon-expandable frame via a skirt. Pre-stenting in the IVC is required to act as an anchoring zone for the valve.[67]
Clinical and echocardiographic outcomes: multiple case reports have shown optimal results for the Sapien valve in reducing TR severity. Loyalka *et al*.[68] reported a case of a 49-year-old woman with severe TR and a previous bioprosthesis failure receiving a transcatheter Sapien valve. Post-intervention echocardiographic results showed substantial improvements in the transvalvular gradient (14.5 to 2 mmHg), RAP (28 to 15 mmHg), and A-wave (33 to 19 mmHg), reflecting a significant reduction in the TR severity. Similarly, a case series by Chandavimol *et al*.[69] found the Sapien valve to be a successful and effective TTVR option in five patients. The results of the post-implantation assessments demonstrated notable improvements in NYHA functional class for all patients. Additionally, echocardiographic findings indicated enhanced right heart function with improvements in multiple parameters, including TAPSE and transvalvular gradient.
Nevertheless, the TRICAVAL trial,[70] which was designed to evaluate the safety and efficacy of Sapien XT implantation in the IVC, was terminated before completion due to a high incidence of valve dislodgement (in 4 of total 14 patients). Moreover, the HOVER trial[71] is currently in progress, aiming to assess the safety and efficacy of the Sapien XT device at IVC.

TricValve system

The TricValve system (P+F Products+Features, Austria) is a bicaval TTVR system that consists of two independent, self-expanding bovine pericardial tissue valves, each of which is designed for deployment in the IVC and SVC, respectively. In consideration of the low-pressure system in IVC, the TricValve stent generates minimal radial force, thus allowing for deployment without the necessity of predilation in the intended landing zone.[72]
Clinical outcomes: the TRICUS EURO study[73] evaluated 35 patients undergoing the TricValve system implantation for treatment of TR. The results revealed a procedural success rate of 94% with no device-related mortality at 6-month follow-up. There was a statistically significant increase in KCCQ score (42.01±22.3 to 59.7±23.6; p=0.004) and a non-significant improvement in the 6MWD. Additionally, with a notable improvement in NYHA functional class, 79.4% of patients exhibited functional class I or II at 6-months (in comparison to 0% at baseline). Another single-center experience study[74] revealed favorable clinical outcomes after the TricValve implantation in 13 patients. With a procedural success rate of 100%, the results demonstrated a notable improvement in symptoms over time, with 82% of discharged patients in NYHA class I and II (compared to 100% in NYHA class III and IV at baseline).
Echocardiographic outcomes: the echocardiographic results in the single-center experience study[74] by Mauro *et al*. showed significant reductions in the right ventricular diame-

ter (43 to 38 mm; p=0.01), and hepatic vein backflow (91% to 45%; p=0.05), reflecting substantial improvement in the TR severity. However, the post-interventional results from the TRICUS EURO study[73] indicated that the majority of parameters demonstrated non-significant changes compared to the baseline. A significant reduction was observed in the hepatic vein backflow (97.0% to 52.9%; p<0.001), whereas the right atrial diameter (68±1 to 69±12 mm; p=0.5), right ventricular end-diastolic area (22.4±7 to 23±7 cm^2; p=0.9), and right ventricular end-systolic area (11.5±3 to 12±5 cm^2; p=0.4) demonstrated a tendency towards increment, indicating a decline in right heart function. Similar findings were reported by Jin et al.[75] in a case report that showed an increase in RAV and basal right ventricular diameter following implantation with the TricValve system.

Emerging transcatheter tricuspid valve interventions

Emerging TTVR options

TriSol valve system

The TriSol valve (TriSol Medical Ltd., Israel) is a TTVR option that has a nitinol stent with a single bovine leaflet attached to two central commissures, creating a bicuspid prosthesis. In order to engage and secure the dome-shaped valve between the adjacent walls and the native leaflets, the nitinol frame employs an inner waist and circumferential fixation arms. The first-in-human experience with the TriSol valve is reported by Vaturi *et al*. in a case report.[76] With significant reduction in TR severity, the post-procedural echocardiographic results at two weeks demonstrated that the valve remained correctly positioned and exhibited low-pressure transvalvular gradients. Additionally, stable right ventricular function was observed, and a reduction in RV size was evident after 24 hours, showing acute reverse remodeling.

TriCento system

The Tricento system (New Valve Technology, Germany) is a transcatheter bicaval valve system consisting of a self-expanding nitinol stent frame covered internally by a thin layer of porcine pericardium. Its design is based on the specific anatomy of each individual patient, with a custom length extending from the superior vena cava to above the hepatic vein.[77] A multicenter registry[78] assessed the outcomes of 21 high-risk patients who underwent Tricento implantation for severe TR. The technical success rate was 100%, with no cases of in-hospital mortality. Additionally, 65% of patients demonstrated improvement in NYHA class I/II (p<0.001). However, echocardiographic follow-up by TTE showed no significant changes in the function or dimensions of both right and left ventricles.

TriCares/Topaz system

The TRiCares/Topaz valve (TRiCares SAS, France) is an orthotopic TTVR system consisting of a self-expanding bovine pericardial valve anchored on a nitinol frame. The outer stent provides an impermeable attachment to the native tricuspid apparatus, while the inner stent contains the trileaflet valve itself. The case report by Teiger *et al*.[79] was the first-in-human experience study for the TRiCares system, with findings indicating favorable outcomes following implantation.

CroiValve DUO system

The CroiValve DUO system (Croivalve, Ireland) is a novel approach that integrates repair and replacement procedures to achieve the most optimal treatment for TR. It consists of a coaptation valve for filling the regurgitant orifice and a supporting anchor system, making it a hybrid device that can be implanted in the SVC and function as a coaptation device at the valve level. The TANDEM I[80] trial is a multicenter study that evaluated the safety and performance of the CroiValve DUO system in 10 patients with severe TR. The six-month results showed a considerable reduction in TR severity, with TR reduced to moderate or less in over 85% of patients. Additionally, patients exhibited a notable improvement in functional outcomes, as highlighted by a significant increase in both the KCCQ score and the 6MWD compared to baseline. The TANDEM II (NCT05913908) enrolling 15 patients is an early feasibility study that aims to assess the efficacy and safety of the CroiValve DUO system.

VDyne system

The VDyne valve system (VDyne Inc., USA) is a TTVR device that consists of a dual-frame nitinol prosthesis housing a porcine trileaflet valve. The device is designed to maintain and preserve the asymmetric shape of the tricuspid annulus and right ventricle. The VISTA-US study,[81] enrolling an estimated 35 patients, aims to test the safety and clinical efficacy of the VDyne system in the treatment of symptomatic severe TR.

Trillium device

The Trillium device (Innoventric, Israel) is a novel endoprosthesis for TR and a caval implantation device that is deployed from the SVC into the IVC. The device is fluoroscopy dependent and eliminates the need for echocardiographic guidance during implantation as it contains fluoroscopic markers along its structure for easy positioning. The first-in-human clinical trial (NCT 04289870) of the Trillium device, which enrolled more than 20 patients, has completed but not yet reported results.

Myvalii™ system

The Myval™ transcatheter heart valve (THV) (Meril Life Sciences, India) is a balloon-expandable device that works in a similar fashion as the Sapien system. The device consists of a

trileaflet structure made from bovine pericardium, a cobalt-chromium alloy frame, and a pericardial skirt at the base of the frame to minimize the risk of paravalvular leak. Although the device is mainly used for aortic positioning, a case report[82] has demonstrated technically feasible and safe valve-in-valve implantation of the Myval™ THV in the tricuspid position.

Laplace system

The Laplace system (Laplace Interventional, Inc., USA) is a TTVR device that consists of an anchoring tab, engagers, and an inner circular valve with tissue overlap between the flaps. The device is equipped with a dedicated delivery system that also includes a steerable catheter, a rail system, and a stabilization system. Initial results from the early feasibility study (NCT06183684)[83] of the Laplace system for severe TR in three patients indicated favorable outcomes at a 30-day follow-up. All the patients were able to achieve improvements in their NYHA functional class and TR grade. Additionally, post-procedural echocardiographic parameters showed substantial improvements, including RVEDD (50±11 to 37±3.6 mm), IVC diameter (32.5±6.1 to 20.7±4.0 mm), and TAPSE (18.3±5.5 to 21±3.6 mm), reflecting enhanced right heart remodeling.

TriFlo system

The Tricuspid Flow Optimizer (TriFlo) system (Triflo Cardiovascular, USA) is a unique device that consists of three anchors that are located at the commissures of the tricuspid valve and polymer leaflets. The anchors support the central flow optimizer, which aims to specifically target the EROA in systole. The results from the 6-month follow-up of the first-in-man compassionate use of the TriFlo system[84] revealed notable improvement in TR severity and positive reverse remodeling of the right heart in echocardiography. Similarly, the first-in-human Italian experience[85] with the TriFlo system showed favorable outcomes in three patients. The results reported a reduction in TR severity, enhanced KCCQ scores and 6MWD, and improvements in echocardiographic parameters including IVC diameter, TAPSE, tricuspid annular diameter, and RAV.

Melody system

The Melody heart valve (Medtronic Inc., USA) is an FDA-approved bovine venous valve that is sutured to a platinum-iridium stent and is commonly used in the transcatheter replacement of pulmonary valves. Multiple case reports[86-87] have reported favorable clinical and echocardiographic outcomes with the transcatheter use of the Melody system for TR.

Emerging TTVr options

Mistral system

The Mistral device (Mitralix Ltd., Israel) is a single-piece, spiral-shaped implant made of nitinol wire that improves the coaptation defect by grasping the chordae of the tricuspid valve leaflets and approximating them. The first-in-human experience study[88] results at 30-day follow-up indicated significant reductions in the TR severity grade, EROA (0.52 to 0.15 cm^2; $p<0.01$), VC width (0.95 to 0.62 cm; $p<0.05$), and regurgitant volume (49.4 to 19.7 ml/beat; $p<0.01$). In addition, significant improvements in NYHA functional class, KCCQ score, and 6-minute walk test were observed, and right ventricular fractional area change (FAC) improved from 27.0% at baseline to 38.5% at 30 days ($p<0.05$).

DaVingi™ TR system

The DaVingi™ TR system (Cardiac Implants LLC, USA) is a transcatheter device aimed at placing an annuloplasty ring to the atrial side of the tricuspid valve through the internal jugular vein. After 30 days of implantation, fibrous healing strengthens the valve, which is then contracted and adjusted. A case report[89] showed significant improvements in the RVEDD, VC width, EROA, tricuspid annular diameter, and TR severity after the implantation of the DaVingi™ TR system at 1-year follow-up. The first-in-human study will evaluate the safety and efficacy of this system in 15 patients with severe TR (NCT03700918).[90]

TRAIPTA system

The transatrial intrapericardial tricuspid annuloplasty (TRAIPTA) system is an experimental TTVr system designed to deliver the implant along the atrioventricular (AV) groove within the pericardial space. Access is obtained by puncturing the right atrial appendage; subsequently, the device is tightened and secured in place with a sliding Roeder's knot. Following implantation, the degree of the tricuspid annular constriction and TR can be changed by modifying the tension forces on the implant. An experimental study[91] using the TRAIPTA system was carried out in 16 pigs, 4 of which had a functional TR. The results showed significant reductions in the severity of TR, the area (59%) and perimeter (24%) of the tricuspid annulus, and septolateral (49%) and anteroposterior (31%) dimensions of the tricuspid valve, respectively ($p<0.001$).

PASTA system

Pledget-assisted suture tricuspid annuloplasty (PASTA) is a transcatheter approach that is currently under development and based on Hetzer's double orifice suture technique. The procedure involves the delivery of pledgeted sutures through a transcatheter approach to approximate the septal and lateral tricuspid annulus. The sutures are then tightened using the Cor-Knot device (LSI Solutions, USA) to reduce the TV orifice.[92] A first-in-human case report of the PASTA system[93] in a patient with torrential TR showed significant reductions in VC width (23 to 1 mm) and the annular area (1817 to 782 mm^2). However, the annulus dehisced and the TR symptoms persisted in the patient.

MIA system

The minimally invasive annuloplasty (MIA) device (Micro Interventional Devices, Inc., USA) is composed of multiple PolyCor™ anchors and a thermoplastic MyoLast™ elastomer. The device is deployed in the tricuspid annulus, and the annulus is plicated by mechanical tension, thus affecting the bicuspidization annulus and reducing annular dimensions. The STTAR study[94] evaluating the efficacy and safety of the MIA device in 31 patients has reported favorable clinical and echocardiographic outcomes. A substantial reduction in the tricuspid annular area (15.88 to 11.71 mm^2) and notable improvements in the TR grades and quality of life were reported at the 12-month follow-up.

TASTI technique

The transcatheter Alfieri stitch for tricuspid insufficiency (TASTI) is a technique similar in action with the TriAlign system and based on a procedure known as transapical leaflet traversal. Guidewires are used in this procedure to pass through the lateral and septal leaflets, which are subsequently captured and replaced with stitches that add pledgets on the right atrial side.[11]

K-Clip system

The K-Clip system (Huihe Medical Technology, China) is based on the principle of annuloplasty. It consists of an external deflectable sheath placed in the right atrium through which an internal sheath with a clip is introduced. The clip is stationed in the annulus between the leaflets with a catheter guarding the right coronary artery (RCA). Once deployed, the clip shortens the circumference of the tricuspid annulus without producing coronary stenosis.[95] An observational study[96] of 39 patients with TR reported a 100% technical success rate for the K-Clip system with no mortality at 30-day follow-up and improvement for all patients in the TR severity grade by at least >1 grade. Post-interventional TEE measurements showed significant reductions in the regurgitant volume (71.1±38.7 to 36.2±23.4 mL; $p<0.05$), EROA (99.5±77.8 to 43.8±27.2 cm^2; $p<0.05$), VC width (12.7±5.7 to 7.0±3.8 mm; $p<0.05$), IVC diameter (22.0±7.1 to 17.8±7.6 mm; $p<0.05$), and right ventricular diameter base (45.8±7.6 to 40.5±8.4 mm; $p<0.05$).

Dragonflyi™ system

The DragonFly™ system (Venus Medtec, China) is an emerging transcatheter edge-to-edge repair device that is currently being used for mitral regurgitation. The device features a central nitinol spacer and leaflet grasping arms, which are designed to improve leaflet coaptation without pulling the leaflets. A multi-center randomized controlled trial (NCT05556460) and a feasibility study (NCT05671640) to evaluate the safety and effectiveness of the DragonFly™ transcatheter system in the treatment of TR are currently underway.

StarTric system

The StarTric repair system (StarTric Ltd., Italy) is a novel TTVr approach based on the Clover technique used for tricuspid valve repair. This technique consists of suturing the midpoint of the free edges of the tricuspid valve leaflets together to create a cloverleaf-shaped valve opening.[97] The StarTric system aims to combine the safety of a minimally invasive device with the efficacy of the Clover technique. The device is currently under development and not available for clinical use.

Pivot-TR device

The Pivot-TR system (Tau-PNU Medical Co., South Korea) is a spacer device that comprises a pivot axis with a nitinol wire backbone and a 3D leaflet with an expandable cylindrical mesh. A preclinical experience with the Pivot-TR device[98] showed significant TR reduction in 14 animals.

TriPair system

The TriPair system (Coramaze Technologies, Israel) consists of a central spacer balloon to fill the coaptation gap along with a retrievable a-traumatic crown. The device is fluoroscopy-based and can be used swiftly without the need for imaging such as TEE/TTE. It has not yet been used in humans.

Technique limitations and future directions

While the full spectrum of complications remains unclear due to the relative novelty of TTVI, several common risks and precautions apply to all devices. Given the close proximity of the RCA, AV node, and noncoronary sinus of Valsalva to the tricuspid valve,[99] transcatheter procedures require careful navigation to minimize the risk of conduction abnormalities, major bleeding, and valvular thrombus formation. Additionally, TTVI is associated with a higher risk of RV systolic dysfunction and pulmonary hemodynamic changes, which can contribute to HF progression.[100] Other potential complications include electrical injuries, paravalvular leaks, and device malfunctions, all of which require further investigation and refinement of procedural techniques.

Moreover, with the increasing use of TTVR and TTVr devices, steps for enhancing the durability and long-term performance of the implants become necessary. The utilization of better leaflet and frame materials, advanced anti-calcification treatments, and optimized anchoring mechanisms can help minimize the risk of device erosion and failure. Simultaneously, it is imperative for physicians to make a patient-tailored choice for an appropriate TTVI strategy that takes into account the individual patient's anatomy, right ventricular function, and comorbidities. Additionally, enhanced use of imaging modalities including CCT, CMR, and echocardiography can improve pre-procedural planning, device delivery, and post-procedural monitoring. Similarly, awareness regarding early intervention could prevent the pro-

gression of TR, potentially improving long-term outcomes. Lastly, the integration of artificial intelligence tools and machine learning in this field can revolutionize patient care, procedural success, and outcome prediction.

Conclusions

The advent of TTVI presents a promising solution to the unmet clinical need for a safe and effective TR treatment. Studies and clinical trials have shown that both TTVR and TTVr interventions demonstrate clinical efficacy with encouraging post-intervention echocardiographic outcomes. However, further research is needed to refine patient selection criteria, determine the optimal timing for intervention, and evaluate long-term clinical outcomes and device durability. A multidisciplinary approach, supported by well-defined guidelines, could drive a transformative shift in the management of the «forgotten valve».

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