



# Innovations in transcatheter tricuspid valve interventions: what has failed, what has worked, what is coming

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Innovation in transcatheter tricuspid valve intervention has advanced by learning from what did not work and expanding what does. Early attempts, often adapted from the mitral space, exposed practical constraints and safety tradeoffs that underscored how distinct the tricuspid valve is in anatomy, imaging, and physiology. Transcatheter edge-to-edge repair has shown improvement in symptoms, health status, and functional capacity with a favorable safety profile, when anatomy is suitable. Orthotopic transcatheter tricuspid valve replacement (TTVR) reliably abolishes regurgitation across complex anatomies, while ongoing iteration targets pacemaker rates, delivery system size, and right ventricular function. Heterotopic bicaval systems relieve venous congestion for patients unsuited to orthotopic solutions. These modalities are complementary in practice: repair is preferred when leaflet anatomy permits, TTVR is definitive when repair is unlikely to succeed, and caval approaches expand options for advanced disease. Looking ahead, the field is converging on devices and workflows that are simpler, smaller, and more anatomy-agnostic, with renewed interest in physiology-guided designs across new annuloplasty, replacement, spacer, and caval platforms. Longer-term readouts from randomized programs will test durability, right-sided remodeling, and hospitalization effects. Finally, responsible dissemination that emphasizes imaging expertise and structured pathways will be essential as access grows. Taken together, the field has moved from exploratory ideas to proven solutions and a credible near-term pipeline, positioning transcatheter therapy to deliver durable, patient-centered benefit for tricuspid regurgitation.

**Keywords:** Tricuspid regurgitation (TR); transcatheter tricuspid valve interventions; tricuspid valve replacement; transcatheter edge-to-edge repair; annuloplasty



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## What has failed

The formative period of transcatheter tricuspid valve intervention was necessarily exploratory, with mitral-derived concepts and early setbacks driving iteration and a deeper understanding of tricuspid anatomy and physiology rather than immediate success. These lessons from early experience explain the therapies that now work and define the boundaries within which the next generation is likely to succeed. Against that backdrop, four areas illustrate how early lessons redirected the field.

One of the clearest examples of early obstacles came from transcatheter direct annuloplasty as performed with the Cardioband system (Edwards Lifesciences, Irvine, USA), where technical complexity and imaging limitations tempered initial enthusiasm despite a strong physiological rationale. The procedure required sequential placement of multiple anchors along the atrial aspect of the annulus followed by mechanical cinching, resulting in lengthy and technically unforgiving interventions. Intra-procedural imaging proved a major rate limiter: bulky delivery

catheters created acoustic shadowing, and anchor position and depth were difficult to confirm. These challenges were compounded by the absence of a robust fibrous scaffold within the tricuspid annulus, contributing to anchor instability and band dehiscence despite measurable annular reduction and clinical improvement. Consequently, adoption remained limited and procedural scalability proved difficult, and after more than a decade of experience, continued large-scale development appears to have slowed. Importantly, these limitations reflect challenges of device execution rather than shortcomings of the underlying physiologic concept. Because annular dilatation remains the principal driver of secondary TR, annuloplasty continues to represent a physiologically important therapeutic strategy, with accumulated experience clarifying the engineering and workflow constraints that future platforms must overcome to achieve reproducible transcatheter implementation.

Second, orthotopic transcatheter tricuspid valve replacement (TTVR) showed that near-complete elimination of tricuspid regurgitation (TR) is possible across anatomies, but at the price of a consistent signal of new permanent pacemaker implantation in pacemaker-naïve patients (1). Mechanistically, this is plausible in the tricuspid position, where the absence of a complete circumferential fibrous annulus and the close proximity to the conduction system make annular radial force-dependent replacement platforms more likely to inflict conduction disturbances (2). Also, TTVR in patients with pre-existing pacemakers can cause transvalvular lead dysfunction, requiring a personalized management strategy (extraction *vs.* jailing) (3). Dedicated tricuspid systems emphasize lower annular radial forces and conduction-sparing anchoring geometries. In that context, as those features mature, the balance between efficacy and safety is likely to improve.

Third, long-term residual TR has tempered positive early outcomes with tricuspid transcatheter edge-to-edge repair (T-TEER). In the initial TRILUMINATE (Trial to Evaluate Treatment With Abbott Transcatheter Clip Repair System in Patients With Moderate or Greater Tricuspid Regurgitation; NCT03227757) single-arm experience, 71% of patients achieved moderate or less TR at one year, and early U.S. experience with PASCAL reported 52% with moderate or less TR at 30 days (4,5). Equally important, contemporary trials and registries show a graded relationship between residual TR and outcomes: patients discharged with none/trace or mild TR accrue larger health-status gains and fewer heart-failure hospitalizations than those with persistent moderate-severe TR (6,7). Consistent

with this evolution, as programs have matured, the likelihood of achieving durable TR reduction has increased, tracking with advances in patient selection, intraprocedural imaging, center experience, and device iteration. The lesson is that residual TR is largely modifiable rather than an intrinsic limitation of leaflet repair. See section “What has worked” for detailed references and context.

Fourth, early transcatheter replacement efforts were constrained by large delivery profiles and invasive access strategies that reflected the infancy of right-sided device engineering. Initial systems such as the GATE (NaviGate Cardiac Structures, Lake Forest, USA) required very large-bore delivery (up to 42 Fr) and implantation through transatrial or transjugular surgical access, limiting procedural safety and broad applicability (8). These experiences highlighted the vulnerability of frail TR populations to bleeding and access-related complications. Subsequent device generations have therefore focused on lower-profile delivery systems, and refined valve crimping and loading mechanisms.

Finally, caval valve implantation (CAVI) was conceived to block systolic backflow into the caval circulatory system and relieve venous congestion in patients unsuitable for orthotopic therapy. Early programs that used balloon-expandable aortic valves for inferior vena cava (IVC) implantation demonstrated feasibility but also migration and embolization, no change in native TR, and early termination in randomized evaluation of IVC-only strategies (9). The inflection point came with dedicated, self-expanding bicaval systems with improved anchoring due to dedicated designs for the cavo-atrial junction. However, the concept is still finding its precise fit in the current landscape.

Early experience was marked by setbacks that delayed, but did not derail, the field. Clinicians and engineers continued to refine concepts, adapt techniques, and redesign devices rather than abandon the space. That persistence transformed early challenges into a foundation for the therapies that followed. With that context, the narrative turns to what has worked and then to what is coming in the future.

## What has worked

### Introduction

The emergence of transcatheter therapies has dramatically reshaped the management of TR. For decades, patients with severe TR were left with few viable options beyond medical therapy, which rarely alters the disease trajectory, or surgery,

which carries substantial morbidity and mortality (10-14). The recent progress in transcatheter tricuspid interventions has therefore been transformative, offering less invasive solutions to a population historically undertreated and often rejected for surgical intervention (15,16).

Among the various transcatheter strategies investigated, two approaches have demonstrated the most consistent and reproducible success in clinical practice: T-TEER and TTVR. Both therapies are now supported by a growing body of multicenter registries and randomized trials, and importantly, both have received regulatory approval in the USA and Europe, marking a decisive shift from experimental therapy to mainstream clinical adoption (17,18). Although representing a narrower niche, heterotopic CAVI has emerged as a palliative option for select patients with torrential TR and prohibitive anatomy for orthotopic repair or replacement.

Taken together, these advances underscore that transcatheter tricuspid interventions are no longer experimental but proven therapeutic strategies. The following subsections will examine in detail the evidence, outcomes, and practical considerations for T-TEER, TTVR, and CAVI, highlighting the progress achieved and the lessons learned in the field so far.

### Transcatheter edge-to-edge repair

Secondary TR is most commonly the result of annular dilation, leaflet tethering, or both, leading to inadequate leaflet coaptation and regurgitant backflow from the right ventricle to the right atrium. The concept of edge-to-edge leaflet repair was pioneered in mitral valve surgery through the Alfieri “stitch” technique and subsequently adapted into transcatheter mitral repair systems. Translating this concept to the tricuspid valve has been attractive given its relative procedural simplicity compared with mitral intervention, as it avoids transseptal puncture and complex left atrial navigation.

Yet, the tricuspid valve presents unique anatomical and technical challenges: variable leaflet morphology (often more than three leaflets), large and dynamic coaptation gaps, extensive leaflet tethering, thinner and more fragile leaflets, and a dense subvalvular apparatus (19). Imaging is also more complex, requiring careful sequential placement of devices to avoid acoustic shadowing and maintain visualization throughout the procedure. Unlike their mitral counterparts, T-TEER systems require dedicated delivery platforms with an additional degree of steering to deflect

away from the interventricular septum and achieve coaxial alignment with the tricuspid valve. Despite these challenges, T-TEER has become the most widely adopted transcatheter therapy for TR, supported by robust safety and efficacy data from both registries and randomized trials.

The TRILUMINATE pivotal trial (Clinical Trial to Evaluate Cardiovascular Outcomes in Patients Treated with the Tricuspid Valve Repair System Pivotal; NCT03904147) randomized 350 patients with severe symptomatic TR to TriClip (Abbott) plus guideline-directed medical therapy (GDMT) versus GDMT alone. Using a hierarchical win-ratio approach, the trial met its primary endpoint, driven primarily by quality-of-life gains as assessed by the Kansas City Cardiomyopathy Questionnaire (KCCQ). Importantly, TR reduction to  $\leq$  moderate was achieved in nearly 90% of treated patients at one year. Although the one-year trial results did not show significant differences in hard endpoints such as mortality or heart failure hospitalization, the consistency of symptomatic improvement and the correlation between greater TR reduction and better outcomes underscored the therapy’s value (20).

Two-year follow-up results of the TRILUMINATE pivotal trial confirmed the sustained safety and efficacy of T-TEER. At two years, 84% of device-treated patients maintained moderate or less TR, and health status improvement as measured by the KCCQ was durable, with a mean increase of  $\sim$ 15 points from baseline. Importantly, the annualized rate of recurrent heart failure hospitalizations was significantly reduced in the device group compared with controls [0.19 *vs.* 0.26 events per patient-year; hazard ratio (HR) 0.72,  $P=0.02$ ]. Freedom from the composite endpoint of all-cause mortality, tricuspid valve surgery, or intervention at two years was higher with T-TEER than medical therapy (77.6% *vs.* 29.3%), largely driven by a high rate of crossover interventions in the control arm. All-cause mortality itself was similar between groups ( $\sim$ 18%), and no late device-related complications, such as embolization or thrombosis, were observed (21).

A critical limitation of the trial design, however, was the protocol-allowed crossover of control patients to device therapy after one year. Nearly 60% of eligible control patients ultimately crossed over, which profoundly diluted between-group comparisons at two years (21). Many of these patients had worsening symptoms and higher TR burden at the time of crossover, and while they demonstrated improvement after receiving TEER, their inclusion in the control arm before crossover confounded longer-term analyses of mortality and hospitalization. As a

result, the apparent equivalence in survival between device and control groups must be interpreted cautiously, since the trial was not able to sustain a true untreated control beyond one year. This design feature, while ethically necessary to provide therapy to highly symptomatic patients, remains a fundamental limitation when interpreting the durability of comparative outcomes.

Soon thereafter, the Tri.Fr trial (Transcatheter Edge-to-Edge Repair for Severe Isolated Tricuspid Regurgitation trial; NCT04646811) further validated T-TEER in a randomized setting. Enrolling 152 patients with severe TR, the trial reported significant improvements in a composite clinical score that included New York Heart Association (NYHA) class, patient global assessment, and cardiovascular events. More than 70% of patients treated with TriClip achieved a reduction in TR to mild or moderate at one year, with a parallel rise in KCCQ scores (22). Uniquely, the Tri.Fr study did not allow for patient crossover. As such, two-year follow up data from the study showed a significant reduction in time to first event (composite of heart failure hospitalization, tricuspid valve surgery, or cardiovascular death) in the treatment arm [HR 0.56 (0.36–0.88); log-rank  $P=0.0109$ ] (23).

The findings from both TRILUMINATE Pivotal and Tri.Fr confirm that T-TEER not only alleviates symptoms but also provides reproducible clinical benefit across different health care systems and patient populations.

The PASCAL system (Edwards Lifesciences, Irvine, USA) introduces design features such as a central spacer and broader paddles. It also has a different mechanism of closing, dependent on the elastic properties of its nitinol frame, which provides a dynamic, self-centering force rather than a fixed mechanical lock. Real-world outcomes with PASCAL were reported in the PASTE registry (PASCAL for Tricuspid Regurgitation—a European Registry; NCT05328284), the largest dataset to date including over 1,000 patients (24). At one year, more than 80% of patients had TR reduced to  $\leq$  moderate, and functional gains were durable. Predictors of suboptimal outcomes included baseline torrential TR, coaptation gaps  $\geq 8$  mm, significant tethering, or the presence of transvalvular leads.

The ongoing CLASP II TR trial (Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial; NCT04097145) will provide definitive evidence to support its use in the U.S.

Taken together, the accumulated evidence positions T-TEER as the most established transcatheter treatment for TR today. The therapy offers consistent symptomatic

improvement, reverse remodeling, and quality-of-life benefits with a very low procedural risk. Although randomized trials have not yet demonstrated reductions in mortality, longer-term follow-up is ongoing and will be critical in clarifying whether early symptomatic gains translate into survival benefit. Importantly, the safety and reproducibility of T-TEER make it an appealing first-line strategy when anatomy is favorable, while leaving room for subsequent therapies such as TTVR or heterotopic valves in cases of residual or recurrent TR.

## TTVR

By replacing the native valve and creating a competent orifice, TTVR can achieve near-complete elimination of regurgitation across a wide range of anatomies. This treatment paradigm has particular relevance for phenotypes characterized by large coaptation gaps, advanced leaflet tethering, or prior transvalvular leads where edge-to-edge repair is less predictable. Careful attention to right ventricular (RV) function, pulmonary vascular load, rhythm management, and anticoagulation strategy remains essential for safe adoption and durable benefit in this largely frail population.

The EVOQUE valve (Edwards Lifesciences, Irvine, USA) is the most clinically advanced system—approved for commercial use in both Europe and the United States—and the only platform with randomized trial evidence. Delivered transfemorally through a 28-Fr steerable system, EVOQUE uses nine ventricular anchors and an atrial flange to secure the prosthesis across the annulus and leaflets. It is available in four sizes (44, 48, 52, and 56 mm).

The TRISCEND (Edwards EVOQUE Transcatheter Tricuspid Valve Replacement: Investigation of Safety and Clinical Efficacy after Replacement of Tricuspid Valve with Transcatheter Device; NCT04221490) study was the first prospective, multicenter, single-arm trial to evaluate TTVR. In 176 patients with severe TR, procedural success exceeded 95% and TR reduction to  $\leq$  mild was achieved in nearly all cases. At one year,  $>95\%$  of patients maintained  $\leq$  mild TR, new pacemaker implantation in pacemaker naïve patients occurred in  $\sim 15\%$ , and major bleeding in  $\sim 12\%$  (25). These results established proof of concept and set the stage for randomized evaluation.

Building on the single-arm feasibility experience from TRISCEND, the TRISCEND II pivotal trial (Edwards EVOQUE Transcatheter Tricuspid Valve Replacement: Pivotal Clinical Investigation of Safety and Clinical Efficacy

Using a Novel Device; NCT04482062) randomized 400 patients with symptomatic severe TR in a 2:1 ratio to TTVR with the EVOQUE system plus GDMT versus GDMT alone (26). Participants were elderly (mean age approximately 79 years), predominantly female (~75%), and highly symptomatic, with roughly 70% in NYHA class III or IV and a baseline KCCQ near 50. Atrial fibrillation was present in more than 90%, and the Society of Thoracic Surgeons predicted risk averaged close to 10% for mitral replacement, consistent with high surgical risk. TR was mainly secondary in etiology (about 70%), and more than half had massive or torrential TR at enrollment. Key exclusions included evidence of severe RV dysfunction, severe left ventricular dysfunction (ejection fraction  $\leq 25\%$ ), severe RV dysfunction, and significant pulmonary hypertension (pulmonary artery systolic pressure  $>60$  mmHg by echocardiography or  $>70$  mmHg by right heart catheterization, or pulmonary vascular resistance  $>5$  Wood units).

At 30 days, cardiovascular mortality was 3.1% in the device group versus 0% in controls. Early severe bleeding occurred in 10.4% of device patients, reflecting the 28-Fr transfemoral system. New permanent pacemaker implantation was required in about 25% of pacemaker-naïve patients, consistent with the device's anchoring mechanics and annular oversizing (26). These signals define the current tradeoffs and targets for device iteration, imaging optimization, and anticoagulation strategy.

At one year, 95.3% of treated patients had TR reduced to  $\leq$  mild, a degree of correction not typically achievable with T-TEER in comparable anatomies. The hierarchical primary endpoint favored TTVR with a win ratio of 2.02 [95% confidence interval (CI): 1.56–2.62;  $P < 0.001$ ], indicating a clear overall clinical advantage of EVOQUE plus GDMT over GDMT alone. Subgroup analyses showed amplified benefit among patients with a heart failure hospitalization within the prior year [win ratio 2.57 (95% CI: 1.59–4.16)] and those with torrential TR at baseline [win ratio 2.47 (95% CI: 1.52–4.01)] (26,27). Conventional time-to-event analyses for all-cause mortality and heart failure hospitalization did not reach statistical significance at one year, though numerical trends favored TTVR and curves began to separate, supporting the biological plausibility that eliminating regurgitation confers downstream benefit. At two-year follow-up, intention-to-treat analyses showed no difference in the composite of all-cause mortality or heart failure hospitalization, likely reflecting the high rate of crossover from medical therapy to TTVR after one year.

In analyses accounting for crossover, TTVR was associated with a reduction in the hard clinical outcomes of mortality and heart failure events, with durable TR reduction ( $\sim 95\% \leq$  mild) and sustained improvements in health status (28).

Patient-reported health status improved substantially. Mean KCCQ increased by about 18 points, with the largest gains in quality-of-life and social limitation domains, as well as improvements in the six-minute walk distance (29). Patients with impaired RV function at baseline, particularly fractional area change below 35%, exhibited attenuated improvement in KCCQ, highlighting the importance of timely intervention before extensive RV maladaptation limits reversibility (29).

TRISCEND II establishes orthotopic TTVR as a safe and clinically effective strategy for severe TR that is unsuitable for repair. It achieves consistent elimination of regurgitation with large and durable gains in symptoms and functional capacity. The principal tradeoffs are procedure-related bleeding and conduction disturbances that are inherent to current device profiles and anchoring strategies. As delivery systems are refined, antithrombotic protocols clarified, and longer-term follow-up accrues, these risks are expected to diminish.

The LuX-Valve program (Jenscare, Ningbo, China) is a replacement platform that achieves multi-point, radial-force-independent fixation through three coordinated elements: a tongue-shaped interventricular septal anchor that engages the muscular septum; leaflet-engaging “rabbit-ears” clasps that are positioned under the anterior and posterior leaflets to stabilize the prosthesis and distribute loads across native tissue; and a self-adapting atrial flange on the right-atrial side to improve sealing and limit paravalvular leak (PVL). This unique fixation concept may lessen direct injury to peri-annular conduction tissue compared with annular-engaging systems. The prosthesis houses a 28- or 30-mm internal bioprosthetic valve and is engineered to treat very large annuli, up to approximately 70 mm.

The multicenter TRAVEL (Transcatheter Right Atrial-Ventricular Valve Replacement With LuX-Valve; NCT04436653) study evaluated the first-generation, trans-atrial (via right mini-thoracotomy) LuX-Valve in 126 elderly, high-risk patients with  $\geq$  severe TR. Procedural and device success was 97.6%. At one-year, TR was reduced to mild or less in about 95%, severe bleeding occurred in 11.9% at 30 days, and permanent pacemaker implantation was uncommon at roughly 1.6% (in pacemaker naïve individuals) (30). These findings established proof-

of-concept that septal anchoring can deliver durable elimination of regurgitation with an acceptable safety profile.

The second-generation LuX-Valve Plus transitioned to a fully transjugular delivery, enabling coaxial deployment from the right internal jugular vein into the right atrium and across the tricuspid plane. TRAVEL II (Transcatheter Right Atrial-ventricular Valve rEplacement With LuX-Valve Via Jugular Vein; NCT05194423) is an ongoing study in China designed to confirm outcomes with LuX-Valve Plus.

Outside of China, an international compassionate-use program has characterized LuX-Valve Plus in Europe and North America. In the early multicenter experience of 76 patients, TR was reduced to 2+ or less in 95% at discharge, conversion to surgery occurred in 5.3%, in-hospital major bleeding occurred in 6.6%, and new permanent pacemaker implantation was 5.7% among pacemaker-naïve patients (31). Extended one-year follow-up of 74 patients demonstrated sustained efficacy with TR 2+ or less in 86.5%, NYHA I/II in about 95% of survivors, no additional bleeding events beyond the index hospitalization, and no valve thrombosis or embolization observed (32).

The TRINITY-US trial (TRIAL to evaluate traNsvenous TrIcuspid valve replacemenT With LuX-Valve Plus System—SafetY and Clinical Performance; NCT06568003) is a global study intended to provide regulatory-grade evidence for LuX-Valve Plus. The European counterpart of the TRINITY trial (TRIAL to Evaluate TraNsvenous TrIcuspid Valve ReplacemenT With LuX-Valve Plus System in Patients With Severe or Greater Tricuspid Regurgitation—SafetY and Clinical Performance; NCT05436028) has completed enrollment and publication of the results is expected soon.

The LuX-Valve system has demonstrated durable reduction of TR with an improved safety profile. Observational comparisons suggest lower rates of new pacemaker implantation and major bleeding than annular-based transfemoral orthotopic systems, a biologically plausible signal given septal anchoring and transjugular access, although prospective randomized data and eventually head-to-head evaluation are still needed. With one-year durability now reported and TRINITY underway, LuX-Valve Plus is emerging as a mature and credible global alternative in TTVR.

Evidence from the multicenter TRIPLACE registry underscores the importance of systematic assessment of PVL after TTVR. Moderate or greater PVL occurs in

approximately 6% of cases across several TTVR platforms and is independently associated with increased one-year mortality and worse functional status. These findings have important implications for future device design and procedural optimization aimed at minimizing residual PVL (33).

TTVR represents a paradigm shift in the management of tricuspid disease. Unlike repair-based therapies, which rely on favorable leaflet anatomy, replacement reliably abolishes regurgitation across anatomies once considered prohibitive. TTVR's clinical utility is balanced by procedural risks, particularly conduction disturbances and bleeding, and by uncertainties regarding long-term durability and anticoagulation strategies. In contemporary practice, T-TEER and TTVR should be viewed as complementary: T-TEER as a first-line strategy when anatomy is suitable, and TTVR as the definitive option when repair is unlikely to succeed. With ongoing refinements, broader adoption, and longer-term follow-up, TTVR is poised to play a central role in tricuspid intervention.

### Heterotopic caval valves

Heterotopic CAVI represents a fundamentally different strategy from orthotopic repair or replacement. Instead of addressing the diseased tricuspid valve directly, CAVI involves implantation of prosthetic valves at the cavo-atrial junctions. The physiologic goal is to block systolic backflow of severe TR into the caval system, thereby reducing venous congestion and its downstream sequelae in the liver, kidneys, and gastrointestinal tract. Patients may experience relief of peripheral edema and ascites, improved functional capacity, and better quality of life.

This approach is particularly relevant for patients with severe TR and unfavorable anatomy for orthotopic therapies, such as extreme annular dilation beyond device availability, severe RV dysfunction, or those deemed unsuitable for surgery or repair. Because CAVI is technically simpler than orthotopic TTVR, does not require advanced imaging or general anesthesia, and is feasible even in lower-volume centers, it offers a palliative yet meaningful option in patients otherwise left with medical therapy.

The early TRICAVAL trial (Treatment of Severe TRICuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve) randomized 28 nonoperative patients with severe TR to IVC-only implantation of a balloon-expandable valve (Sapien XT) versus medical therapy. While

feasibility was demonstrated, the trial was stopped early due to device migration and embolization events, and higher mortality in the CAVI arm (9). This experience highlighted the limitations of using non-dedicated aortic prostheses for caval implantation and accelerated the development of dedicated bicaval devices.

The most advanced dedicated system is the TricValve (P&F Products & Features, Vienna, Austria), consisting of two self-expanding bioprosthetic valves designed for the superior vena cava (SVC) and IVC. The devices are mounted on a 27.5-Fr delivery system and covered with a pericardial skirt to minimize PVL. They are positioned at the cavo-atrial junctions with careful attention to avoid obstructing hepatic venous inflow.

The TRICUS EURO trial (Safety and Efficacy of the TricValve Transcatheter Bicaval Valves System in the Superior and Inferior Vena Cava in Patients With Severe Tricuspid Regurgitation) enrolled 35 patients with severe TR and demonstrated procedural success in 94%, with improvements in NYHA class and KCCQ at 6 months (34). The most frequent adverse event was transient shoulder pain, attributed to phrenic nerve compression, but no device-related mortality occurred. One-year outcomes confirmed durability, with ~95% of patients demonstrating improved KCCQ, NYHA class, or six-minute walk distance. Heart failure rehospitalization occurred in 29.5%, but abolition of systolic hepatic vein flow reversal was seen in nearly two-thirds, confirming physiologic efficacy.

Larger-scale evidence was recently reported in the TricBicaval Registry, which included 204 patients across 27 European and Brazilian centers. Procedural success was 96% and 30-day clinical success 83%. At one year, NYHA class I–II improved from 20% to 82%, with marked reductions in edema, ascites, and diuretic requirements. Heart failure hospitalizations were cut nearly in half, from 61 to 27 events per 100 patient-years. Hemodynamically, mean IVC pressure decreased by 3 mmHg and v-wave amplitude by 8 mmHg (35).

In the United States, the TRICAV-I (TRICvalve biCAVal Valve System for Severe Tricuspid Regurgitation; NCT06137807) is a single-arm feasibility study, with enrollment ongoing. TRICAV-II (TRICAV-II Pivotal: TRICvalve biCAVal Valve System for Severe Tricuspid Regurgitation; NCT06458907) is a planned randomized trial that will serve as the pivotal study supporting potential Food and Drug Administration (FDA) approval.

CAVI is unique in that it does not address the underlying valvular lesion but instead targets the hemodynamic

consequences of regurgitant backflow. As such, it should be viewed as a palliative therapy, best suited to patients with severe symptomatic TR who are poor candidates for T-TEER or TTVR. Its major advantages are technical simplicity (i.e., fluoroscopic guidance only), symptom relief, and broad applicability in anatomies unsuited to orthotopic devices. However, limitations include a lack of TR reduction on echocardiography and absent improvement in RV function, making it fundamentally different from repair- or replacement-based strategies. For now, CAVI provides a valuable option for symptom control in patients with few alternatives, complementing the broader landscape of transcatheter tricuspid interventions.

## Conclusions

Taken together, the evolution of T-TEER, TTVR, and CAVI demonstrates how transcatheter innovation has rapidly transformed the treatment landscape for severe TR. Each approach occupies a distinct sector within tricuspid valve disease, but together they establish that transcatheter therapies can deliver durable clinical benefit where surgery was once prohibitive. This foundation now sets the stage for the next wave of innovation, which will focus on refining devices, expanding indications, and personalizing therapy to patient anatomy and physiology.

## What is coming

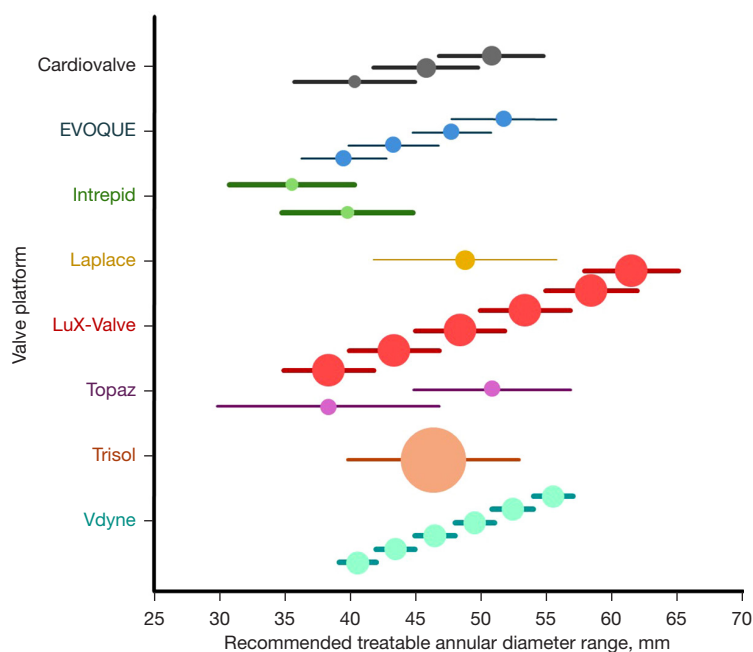
### Introduction

After decades as the ‘forgotten valve’, the tricuspid space has become one of the most dynamic frontiers in structural heart innovation. The result is a pragmatic toolbox adapted to right-sided anatomy and physiology, offering clinically meaningful choices unimaginable just a few years ago.

### Pipeline of new devices

#### *Orthotopic TTVR*

The next phase of TTVR is characterized by rapid diversification of device design, reflecting continued efforts to address the anatomic and physiologic challenges unique to the tricuspid position. Emerging platforms differ substantially in anchoring strategy, delivery profile, treatable annular dimensions, internal valve dimensions, and procedural workflow. A graphical overview of currently available and investigational orthotopic replacement systems is provided in *Figure 1*, with corresponding device



**Figure 1** Comparative device sizing and delivery profiles of available TTVR platforms. Graphical comparison of currently available and investigational orthotopic transcatheter tricuspid valve replacement systems, illustrating the recommended treatable annular diameter range, internal valve diameter, and delivery system profile across platforms. For each device size, the horizontal bar denotes the recommended annular diameter range suitable for implantation. Bar thickness is scaled to the delivery system outer diameter (French size). Circle markers represent discrete valve sizes within each platform, with circle diameter proportional to the internal valve diameter. Detailed device dimensions, delivery profiles, and sizing specifications are provided in *Table 1*. TTVR, transcatheter tricuspid valve replacement.

specifications summarized in *Table 1*. Together, these platforms illustrate an active period of engineering ingenuity aimed at expanding treatable anatomies while improving procedural safety and reproducibility; throughout this section, selected device features are highlighted in bold to draw attention to potential design advantages and intended physiologic or procedural benefits.

#### **Trisol (Trisol Medical, Yokneam, Israel)**

Trisol is a single dome-shaped valve with two commissures and fixation via twelve ventricular support arms plus an atrial ring for axial stability. It is delivered via 31-Fr transjugular access with full recapture and repositioning until final release. The design reduces peak RV pressure gradient ( $dP/dt$ ) with gradual closure of the leaflets and fixed closing volume, which is intended to reduce the risk of RV afterload mismatch. A large internal valve orifice (35 mm at inflow and 45 mm at outflow) provides a large valve area and orifice, which has shown to increase cardiac output in early data. The U.S. early feasibility study (EFS) (Early Feasibility Study of the Trisol System; NCT04905017) is ongoing. The first 17 patients presented at New York Valves

2025 demonstrated none or mild TR in 82% at 30-day follow-up (36).

#### **Topaz (TRiCares, Aschheim, Germany)**

The Topaz system has a two-frame design that pairs a soft outer stent conforming to the native annulus and RV motion with an inner circular frame housing the trileaflet valve and preserving geometry independent of outer-frame deformation. The anchoring system is designed to be atraumatic with minimal radial force to minimize the risk of conduction disturbances. It is secured to the tricuspid valve via two rows of small cleats, which aim to anchor on the leaflet and annulus tissue. Delivery is transfemoral venous via a 29-Fr steerable introducer. In the TRICURE FIH (TRiCares Topaz Transcatheter TRICUspid Heart Valve REplacement System; NCT0512603) completed in 20 patients, 100% achieved none or mild TR at 30 days, no new pacemakers were reported, and mean implant time was only 35 minutes (37). TRICURE EFS (The TRICURE EFS TRiCares Topaz Transfemoral TRICUspid Heart Valve REplacement System Early Feasibility Study; NCT06506942) is enrolling in the United States and

**Table 1** Comparative technical specifications of available TTVR platforms

Device	Device size	Recommended treatable annular range (mm)	Internal valve diameter (mm)	Delivery system outer diameter (Fr)	Access route
Cardiovalve	S	36–45	27	32	Femoral
	M	42–50	29	32	Femoral
	L	47–55	29	32	Femoral
EVOQUE	44	36.5–43	28	28	Femoral
	48	40–47	28	28	Femoral
	52	45–51	28	28	Femoral
	56	48–56	28	28	Femoral
Intrepid	42	31–40.1	27	35	Femoral
	48	35.5–45	27	35	Femoral
Laplace	Single configuration	42–56.4	28	26	Femoral
LuX-Valve	40	35–42	30	33	Jugular
	45	40–47	30	33	Jugular
	50	45–52	30	33	Jugular
	55	50–57	30	33	Jugular
	60	55–62	30	33	Jugular
	65	58–65	30	33	Jugular
Topaz	45	30–47	28	29	Femoral
	55	45–57	28	29	Femoral
Trisol	Single configuration	40–53	35	31	Femoral
Vdyne	0	39–42	30	35	Femoral
	1	42–45	30	35	Femoral
	2	45–48	30	35	Femoral
	3	48–51	30	35	Femoral
	4	51–54	30	35	Femoral
	5	54–57	30	35	Femoral

Device size configurations, recommended treatable annular diameter ranges, internal valve diameters, and delivery system profiles are summarized across platforms. Annular dimension ranges represent recommended treatment ranges and, where applicable, were converted from perimeter-based sizing. Values are derived from manufacturer instructions for use, published reports, and technical specifications presented in scientific meetings and investigator disclosures. L, large; M, medium; S, small; TTVR, transcatheter tricuspid valve replacement.

Canada, and TRICURE EU (The TRICURE EU PIVOTAL TRiCares Topaz Transcatheter TRICUspid Heart Valve REplacement System EUROpean PIVOTAL Study; NCT06581417) is the European pivotal study.

#### **Intrepid (Medtronic, Minneapolis, USA)**

The Intrepid system is adapted from the mitral platform for tricuspid use. It is designed with a dual-stent bovine

pericardial valve mounted within a nitinol dual stent frame. The outer frame is 44 or 48 mm with reduced radial force in the 48 mm size to mitigate conduction system interaction; the inner stent is 27 mm. Anchoring relies on direct annular engagement by radial force and small cleats, eliminating leaflet capture steps and potentially simplifying imaging. Delivery is via a 35-Fr venous capsule, with a 29-Fr system

in development. The EFS (NCT04433065) is recruiting (38).

#### **Cardiovalve (Cardiovalve Ltd., Or Yehuda, Israel)**

The Cardiovalve system is a self-expanding nitinol frame with 24 leaflet grasping points, anchors on native leaflets with low radial force, and features an atrial flange designed to minimize PVL. The prosthesis can treat annuli up to 55 mm (XL valve), delivered by a 32-Fr capsule with a 24-Fr shaft. The TARGET study (Safety and Performance of the Cardiovalve TR Replacement System; NCT05486832) is a prospective, multicenter single-arm evaluation; interim presentation of the first 125 patients reported 94% none or mild TR at 30 days (39).

#### **Laplace (Laplace Interventional, Inc., Plymouth, USA)**

The Laplace system is a self-expanding valve delivered transjugularly through a 26-Fr system, with a posterior flap and engagers and an anterior flap that secures in the RV outflow tract. The device is fully recapturable and repositionable until final deployment. The access strategy transitioned from surgical cutdown to fully percutaneous. It is designed for very large annuli up to 177 mm perimeter. The U.S. EFS (NCT06183684) is underway. In the first 35 patients, median device time was 44 minutes and 87% achieved none or mild TR. The company reported improved access-site related complications and TR outcomes with iterative device and procedural updates during the EFS (40).

#### **Vdyne (Vdyne, Maple Grove, USA)**

The VDYne TTVR system represents a distinct design philosophy, emphasizing an anatomy-conforming prosthesis and novel delivery mechanics. The prosthesis consists of a porcine pericardial bioprosthetic valve mounted within an asymmetric, D-shaped self-expanding frame intended to conform to native right-sided geometry while minimizing radial stress on adjacent structures. The system is available in five external frame sizes (140–180 mm perimeter), each incorporating a standardized 30-mm internal valve diameter.

The device is delivered via transfemoral venous access using a side-loaded delivery system designed to facilitate deployment within the limited working space of the right atrium and ventricle. A shallow implantation profile and fully repositionable, retrievable design permit iterative positioning until final release. The procedural concept is largely independent of leaflet morphology or imaging-guided leaflet interaction, potentially simplifying implantation. An integrated “pop-off” safety mechanism is intended to mitigate acute RV afterload mismatch by allowing controlled pressure adaptation following valve

deployment.

Clinical experience derives from the VISTA-US and VISTA-GLOBAL EFS (Clinical Safety and Efficacy of the VDYne Transcatheter Tricuspid Valve Replacement System for the Treatment of Tricuspid Regurgitation; NCT05848284 and NCT05797519), which together enrolled 62 patients with symptomatic TR. Device or technical success was achieved in 91.9% (57/62). Among pacemaker-naïve patients, new permanent pacemaker implantation occurred in 13.5% (7/52). At 30 days, 82% of treated patients demonstrated reduction of TR to less than mild severity (41). Ongoing engineering refinements aim to reduce procedural time and further improve device securement and deployment consistency.

#### ***Heterotopic TTVR***

##### **Trillium (Innoventric, Rehovot, Israel)**

The Trillium system is a covered stent system that spans the cavo-atrial junction and incorporates three right-atrial openings oriented toward the native tricuspid inflow, allowing antegrade venous return while shielding the cava from systolic backflow. In a first-in-human series of 20 patients (median age 81 years), implantation success was 100% with no intraprocedural deaths. Hemodynamics improved with central venous pressure (CVP) mean decreasing from 19 to 17 mmHg and v-wave from 28 to 21 mmHg, both significant. At the device level, TR was mild in all patients at discharge and maintained at 30 days, while regurgitant volume decreased from 61 to 39 mL. Thirty-day outcomes included one death, two heart-failure hospitalizations, two dialysis starts, and two major bleeds, with improvements in NYHA class and a trend toward better quality of life (42). Building on this platform, iterative designs such as Koala™ and Unica™ aim to expand applicability and procedural flexibility. Koala™ incorporates a cross-caval docking system to facilitate stable anchoring in both the SVC and IVC and enable implantation of off-the-shelf valves, while Unica™ is designed for smaller anatomies and introduces a bare-metal central structure that preserves access for future transeptal interventions and valve-in-valve procedures. Early experience with both systems remains limited to compassionate use.

#### ***Spacer***

##### **DUO (CroiValve, Dublin, Ireland)**

The DUO system is a two-component spacer platform designed to address severe TR while preserving native valve anatomy. The first component, a coaptation valve, occupies the regurgitant orifice, allowing the native leaflets to seal

against its outer pericardial skirt to prevent systolic backflow while maintaining diastolic flow. The second component is an anchoring system, in which an adjustable catheter suspends the coaptation valve within the tricuspid annulus and is stabilized by a stent positioned in the superior vena cava. The device is delivered via transjugular access and fixed according to the coaptation gap.

The TANDEM I (A European Feasibility Study of the CroiValve DUO Transcatheter Tricuspid Coaptation Valve System in Patients With Tricuspid Regurgitation) first-in-human study enrolled 11 patients. Two patients required early reintervention due to undersizing of the SVC stent; after the anchor design was modified and oversizing strategy adopted, no further such events occurred. The mean device time was 43 minutes (range, 34–58 minutes). Residual moderate TR was common in this early experience (43). The TANDEM II (Early Feasibility Study of the DUO Transcatheter Tricuspid Coaptation Valve System in Patients With Tricuspid Regurgitation; NCT05913908) EFS is currently enrolling.

#### **TriPair (Coramaze Technologies, Or Yehuda, Israel)**

The TriPair system is a leaflet-to-spacer repair concept that positions a self-centering, flexible central spacer within the coaptation gap to facilitate leaflet closure. The system uses atrial fixation and a non-rigid architecture to maintain spacer position across the cardiac cycle and to make efficacy less dependent on valve size and morphology. The first-in-human cohort of 10 patients demonstrated short procedure times and no 30-day major adverse events with effective TR reduction. A next-generation delivery system has been used successfully in initial cases and is focused on procedural simplification and reproducibility (44).

#### **Versa Vascular (Versa Vascular, Irvine, USA)**

The Versa Vascular system represents a hybrid repair concept positioned between spacer-based therapy and annular remodeling. Delivered transfemorally through a 26-Fr catheter, the device consists of a conformable nitinol atrial frame with anchoring barbs and a textile skirt designed to promote tissue ingrowth and limit progressive annular dilation. A centrally positioned 22-mm disk reduces regurgitant flow by partially occupying the regurgitant orifice while preserving a large residual geometric orifice area ( $>8 \text{ cm}^2$ ). This dual mechanism—annular stabilization combined with flow reduction—aims to decrease TR severity without valve replacement or leaflet grasping.

First-in-human implantation demonstrated procedural feasibility with reduction of torrential TR to moderate severity and improvement in functional status at 90 days,

without adverse effects on RV function (45). Limitations include difficulty in assessing residual TR due to jet splitting, potential challenges with future right-sided catheter manipulation or placement of pacing leads because of the fixed atrial frame and central disk, and the inability to reposition or retrieve the device after release. Early device iteration has increased atrial fixation elements and frame dimensions to improve stability and accommodate larger annuli.

#### **Annuloplasty**

In secondary TR, the dominant pathology is annular dilatation, especially in the anteroposterior region along the RV free wall. The annulus becomes larger, more circular, and flatter, which prevents otherwise normal leaflets from coapting. Reducing and reshaping the annulus directly shrinks the coaptation gap and re-establishes leaflet contact even when some leaflet tethering persists. By interrupting the vicious cycle of TR leading to RV volume overload, which leads to further annular stretch and ultimately worsening TR. Annuloplasty can stabilize right-sided geometry early and help promote late, reversible remodeling. Accordingly, contemporary surgical guidelines recommend concomitant tricuspid annuloplasty at the time of left-sided valve surgery in patients with severe or moderate TR, and in those with mild TR with significant annular dilatation ( $\geq 40 \text{ mm}$  or  $>21 \text{ mm/m}^2$ ), given the observed risk of progression and persistence when the annulus is left untreated (46–48). Surgical literature remains supportive of the concept of annular reduction, with ring annuloplasty showing sustained TR reduction and superior freedom from TR recurrence compared with suture bicuspidization in long-term series, which frames the physiological basis for a catheter-based annuloplasty ring (49,50).

Direct transcatheter annuloplasty with the Cardioband (Edwards Lifesciences, Irvine, USA) device uses a sutureless polyester band mounted on a delivery system that is anchored sequentially on the atrial side of the tricuspid annulus from anterior to posterior, then mechanically cinched to reduce septolateral diameter and coaptation gap. Imaging and intraprocedural execution are significantly more complex than T-TEER, since anchor placement, alignment, and depth must be accurate to avoid adjacent structures and to create symmetric annular reduction. Posterior anchor delivery can be challenging because of acoustic shadowing from left-sided prostheses and catheter artifact; four-dimensional intracardiac echocardiography (4D-ICE) can mitigate these limitations by bringing the

imaging plane closer to the annulus. The right coronary artery imposes an anatomic constraint for anchor trajectories and length selection.

The one-year early feasibility experience reported device success of 92% and procedural success of 83%, with a long median device time of 189 minutes (range, 93 to 448 minutes). Severe bleeding occurred in 21.6% at 30 days, with two events being life-threatening. Annular reduction was significantly reduced by 21% at one-year (mean septolateral TV annulus diameter from 45.6 to 35.1 mm,  $P < 0.001$ ). TR reduction was modest but progressive, with 44% achieving mild or moderate TR at 30 days and 73% at one year, and NYHA I–II increasing from 31% to 78% (51).

Additional devices are in development to meet the perennial challenges of a direct annuloplasty that is imaging-friendly, reproducible, and straightforward to use. The DragonRing system (Valgen Medtech, Hangzhou, China) is a transseptal direct annuloplasty platform conceptually similar to Cardioband; it deploys repositionable and retrievable atrial-side anchors along the annulus and uses a polymer-coated spacer with a controllable contraction wire to effect septolateral reduction (51). The Tri-Ring system (Cardiac Implants LLC, Delray Beach, USA) employs a two-stage strategy intended to mitigate dehiscence: Stage I delivers the anchors and ring, then the system is left *in situ* for approximately 90 days to allow endothelialization and tissue ingrowth; Stage II returns for ring cinching to achieve annular reduction. The delayed cinch is designed to give the typically non-fibrous tricuspid annulus time to scar and stabilize before tensioning. The MIA™ system (Micro Interventional Devices, Newton, USA) represents a low-profile transfemoral (12 Fr) annuloplasty approach that functionally reproduces a Kay-type posterior annuloplasty. It employs two self-tensioning polymeric anchors connected by an elastomer bridge that plicates the posterior annulus after deployment, thereby reducing annular dilation without sequential anchor placement. The system is currently under investigation in the STTAR trial (NCT03692598).

Alternative approaches aim to achieve annular remodeling through simplified or indirect mechanisms. The K-Clip™ system (Shanghai Huihe Medical Technology Co., Shanghai, China) is a transjugular (18 Fr) clip-based device designed to mimic Kay's surgical plication by approximating segments of the tricuspid annulus using a single anchor and dual clamping arms. It may be used as a standalone therapy or combined with T-TEER or orthotopic TTVR. Early results from the ongoing TriStar Pivotal Trial (NCT05173233) demonstrated favorable procedural safety

and significant TR reduction at one year, although residual moderate or more TR remained common (82.5%) (52). A distinct conceptual strategy is represented by TRAIPTA (Transatrial Intrapercardial Tricuspid Annuloplasty), an investigational procedure rather than a discrete implant, in which access to the pericardial space via the right atrial appendage allows circumferential deployment of an implant along the atrioventricular groove to externally compress and remodel the annulus; the TRAIPTA EFS (NCT06479824) is ongoing.

Importantly, annuloplasty does not preclude downstream options: case reports have documented both T-TEER after band and TTVR after transcatheter annuloplasty in selected anatomies, underscoring that a band can be the first step in a staged strategy to resize the annulus, then finalize competence with leaflet repair or replacement when appropriate (53,54). A reasonable hypothesis, mirroring surgical practice, is that earlier deployment of transcatheter annuloplasty in secondary atrial TR could improve the long-term performance of subsequent therapies by restoring annular geometry before irreversible RV maladaptation.

### Data on the horizon

The next phase of evidence will determine how these therapies are selected, iterated, and sustained. For TTVR, extended follow-up from early feasibility through the pivotal TRISCEND II cohort is beginning to provide insight into whether durable abolition of regurgitation translates into fewer heart failure events and improved survival, although interpretation of hard endpoints remains influenced by the high rate of crossover from medical therapy. These data also continue to inform valve durability, antithrombotic strategies, and the relationship between imaging findings such as leaflet thickening or subclinical thrombosis and clinical outcomes, while providing insight into RV reverse remodeling. For repair, two-year data now provide a more encouraging clinical signal, although trial design remains important. TRILUMINATE demonstrated durable TR reduction and reduced recurrent heart-failure hospitalizations, but interpretation of longer-term comparative endpoints is constrained by substantial crossover from the control arm. In contrast, Tri.Fr did not allow crossover and demonstrated a significant reduction in the composite clinical endpoint and heart-failure hospitalization at two years, strengthening the evidence that T-TEER benefits may extend beyond symptoms and health status. Durability of TR reduction over several

years remains a key variable to track, especially given the relationship between residual TR and outcomes. Across both strategies, these datasets will sharpen patient selection by quantifying how baseline RV function, pulmonary vascular load, atrial functional mechanisms, transvalvular leads, and related variables influence the stability of TR reduction and the likelihood of sustained clinical benefit.

In parallel, feasibility and pivotal outcomes of TTVR, annuloplasty, spacer, and caval systems will widen the anatomic and clinical range that can be treated. Head-to-head comparisons are unlikely in the near term, but pragmatic designs that use hierarchical composites anchored in health status, functional capacity, and recurrent heart failure hospitalization, with prespecified handling of crossover, can deliver credible clinical signals.

Important European evidence is expected from TRICI-HF (TRICuspid Intervention in Heart Failure Trial; NCT04634266), an industry-independent, multicenter randomized study coordinated by the German Centre for Cardiovascular Research. The trial compares contemporary transcatheter tricuspid interventions against GDMT in patients with symptomatic, high-grade TR and heart failure, with primary endpoints centered on 12-month survival and heart failure hospitalization. Recruitment is complete and follow-up is ongoing across 25 German sites, targeting 360 participants. The design allows crossover from medical therapy to intervention after a qualifying heart-failure admission, reflecting real-world ethics yet raising important considerations for longer-term between-group analyses (55).

Several trial questions merit priority. Randomized comparisons of antithrombotic agents and duration after orthotopic TTVR would standardize practice and may reduce bleeding risk without increasing thrombotic risk. Structured strategies for cardiac implantable electronic device management, including extraction, jailing, or lead relocation, have received significant attention recently, although they should be evaluated prospectively (56). Populations excluded from previous trials, such as patients with advanced pulmonary hypertension or end stage renal disease, require careful consideration for future studies to define potential benefit. Multivalvular disease is common, so staged or combined approaches for mitral and tricuspid pathology should be tested. Finally, earlier treatment of moderate TR and *a priori* staged procedures (annuloplasty followed by T-TEER or TTVR, among other combinations) are areas to look forward to in the extended future. Together, these findings will inform device iteration,

refine patient selection, and guide the health-system deployment strategies outlined in the following section.

### Overall outlook and strategic directions

The field has come a long way since we recognized the clinical importance of the once forgotten valve. Early trans-atrial systems were large, bulky platforms that offered modest technical success with uncertain clinical benefit. In contrast, there are now two FDA-approved therapies with reproducible safety and meaningful gains in symptoms and health status, and a robust pipeline poised to further improve safety, streamline procedures, and expand eligibility on the basis of anatomy and physiology rather than exclusion.

The central question is how to disseminate this technology responsibly without eroding safety, quality, or equitable access. Experience from the comparatively long journey with transcatheter aortic valve replacement and mitral-TEER shows a correlation between center experience and outcomes, which argues for measured deployment for tricuspid interventions (57-59). Uncontrolled diffusion could magnify the volume-outcome gradient, cloud the therapeutic signal, and delay further progress. In the near term, adoption should be anchored in multidisciplinary centers of expertise with experienced interventional cardiologists and imagers, dedicated right-sided heart teams, and standardized pathways for escalation and follow-up. As devices and workflows mature, broader dissemination must proceed with clear training standards, proctoring, and transparent outcomes reporting so that scale does not outpace quality.

A practical rate limiter is workforce. These therapies are imaging-intensive, transesophageal echocardiography (TEE)-guided, and outcomes depend on real-time decisions from skilled and dedicated interventional imagers, yet current reimbursement often overlooks the imager's time and specialized expertise. The path forward should include formalized imaging curricula and certification, protected time for preprocedural planning, and co-primary operator recognition where appropriate.

In summary, a modular toolbox is now within reach. Repair, replacement, spacers, and caval systems are mostly complementary rather than competitive, and can be sequenced to match right-sided anatomy and physiology while preserving future options. If dissemination is organized, imaging capacity is cultivated, and device

design continues to converge on safer, simpler, and more predictable procedures, transcatheter tricuspid intervention is positioned to deliver durable, patient-centered benefit at scale. In this trajectory, what has failed has defined our boundaries, what has worked has established a new standard, and what is coming is a credible path to safer procedures, smarter selection, and better patient care.

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