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Transcatheter edge-to-edge repair in functional tricuspid regurgitation

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TRI fr

Tricuspid edge-to-edge repair (T-TEER) has emerged as a promising treatment option for severe functional tricuspid regurgitation (TR) in patients unsuitable for surgery. Recent findings from randomized clinical trials consistently demonstrated a reduction in TR severity and significant symptomatic improvement with T-TEER, particularly in terms of quality of life and functional status. However, no significant differences in mortality or hospitalizations were observed compared to guideline-directed medical therapy. In this complex scenario, careful patient selection and a comprehensive evaluation of the tricuspid valve remain critical for optimizing outcomes. Patients with preserved right ventricular (RV) function, absence of pulmonary hypertension (PH), and no significant organ dysfunction are more likely to benefit from T-TEER. Conversely, in patients with severe RV dysfunction, lack of contractile reserve, pre-capillary or severe combined post-capillary PH, end-stage organ failure, and significant impairment in daily activities and self-care, the procedure may be futile. Patients in the grey zone should be evaluated by a dedicated heart team, with a tailored decision-making approach.

Introduction

Tricuspid regurgitation (TR), the most prevalent disorder of the tricuspid valve (TV), affects about 0.55% of the population.[1] Functional TR, responsible for over 90% of cases, results from right ventricular (RV) or tricuspid annular dilation, leading to leaflet malcoaptation.

The prevalence of TR is rising due to population ageing, increasing atrial fibrillation rates, and the widespread use of intracardiac devices. TR is independently associated with progressive RV failure and adverse outcomes, posing a growing public health concern. The 2021 European Society of Cardiology (ESC) guidelines recommend surgery for severe TR in combination with left-sided heart procedures or in symptomatic patients with RV enlargement, provided left ventricular, RV dysfunction and pulmonary hypertension are not severe (class of recommendation IIa, level of evidence B).[2] However, isolated TR surgery is associated with high in-hospital mortality, primarily due to late referrals and comorbid conditions.

Transcatheter therapies have emerged as alternatives for high-risk patients with severe TR unresponsive to medical management. Among these, transcatheter edge-to-edge tricuspid repair (T-TEER) is the most widely adopted, supported by growing clinical evidence (*Table 1*).

First T-TEER trials were performed using the TriClip™ (Abbott Structural Heart, Santa Clara, CA, USA). The TRILUMINATE (Trial to Evaluate Cardiovascular Outcomes in Patients Treated with the Tricuspid Valve Repair System) Pivotal trial[3] demonstrated that T-TEER was

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Table 1 Summary table of studies evaluating T-TEER

Name	Study Type	Device	N.	Population	TR Reduction	Results
TRILUMINATE Pivotal (The Trial to Evaluate Cardiovascular Outcomes in Patients Treated with the Tricuspid Valve Re- pair System Pivotal) trial[3]: 1-year follow-up 2023	International, randomized, controlled trial	TriClip	350	Age 78 ± 7 years 59.4% (T-TEER group) - 55.4% (control group) NYHA III/IV 70.7% massive/torrential TR TAPSE > 17 mm 83% (T-TEER group) - 68% (control group) sPAP 39.7 ± 9.2 (T-TEER group) - 40.1 ± 10.1 (control group)	71% reduction to moderate or less	• Statistically significant difference in the primary endpoint between T-TEER and control group (p = 0.02), primarily driven KCCQ improvement (p < 0.001). • No differences in mortality and heart failure related hospitalization between T-TEER and control group . • 98.3% of patients free from major adverse events at 30 days.
bRIGHT (An Observational Real-World Study Evaluating Severe Tricuspid Regurgitation Patients Treated With the Abbott TriClip Device)[4]: 1-year results 2023	Prospective, single-arm, open-label, multicenter registry	TriClip	511	Age 79 ± 7 years 80% NYHA III/IV 88% massive/torrential TR sPAP 40 ± 12 mmHg TAPSE 17 ± 0.4 mm	81% reduction to moderate or less TR	• Improvements NYHA class (p < 0.0001). • Improvements KCCQ score (p <0.0001). • 1 year mortality was significantly lower in patients with moderate or less TR at 30 days.
TRILUMINATE (TRILUMINATE Study With Abbott Transcatheter Clip Repair System in Patients With Moderate or Greater TR)[5]: 3-year results 2023	International, prospective, single arm, multicenter study	TriClip	98	Age 77.5 ± 8.1 years 76% NYHA III/IV 62% massive/torrential TR TAPSE 15 ± 0.3 mm sPAP 38.9 ± 16 mmHg	79% reduction to moderate or less	• Improvements NYHA class (p < 0.0001). • Improvements KCCQ (p = 0.006). • Right chambers reverse remodelling. • 75% reduction of heart failure hospitalization between the period before and after device implantation (p < 0.0001).
TriValve (Transcatheter Tricuspid Valve Therapies)[6]: 1-year outcome 2019	Prospective, multicenter, international registry	TriClip	249	Age 77 ± 9 years 96% NYHA III/IV 51.8% massive TR TAPSE 15.8 ± 4.3 mm	72% reduction to moderate or less TR	• Improvements NYHA class (p < 0.001). • Significant sPAP reduction (p < 0.001). • 20% all-cause mortality • 35% the combined rate of mortality and unplanned heart failure related hospitalization. • Predictors of 1-year mortality were procedural failure, worsening kidney function, and absence of sinus rhythm.
PASTE (PASCAL for Tricuspid Regurgitation - a European registry)[7]: 1 year-results 2024	Investigator- initiated, multicenter, single-device, retrospective and prospective, observational cohort study	PASCAL	1.059	Age 79 ± 9 years 87% NYHA III/IV 96% severe or greater TR TAPSE 17.3 ± 4.2 mm	83% reduction to moderate or less TR	• Improvements NYHA class (p < 0.001). • Improvements 6MWT (p < 0.001). • Improvements quality of life (p < 0.001). • 15% all-cause mortality • 16% heart failure related hospitalization. • Male sex, the severity of residual TR, sPAP echo, abnormal gamma-glutamyl transferase and ascites, were indipendet predictors of mortality and heart failure related hospitalization.
CLASP TR (Edwards PASCAL TrAnScatheter Valve RePair System in Tricuspid Regurgitation [CLASP TR] Early Feasibility Study)[8]: 1-year results 2023	Single-arm, multicenter, prospective study	PASCAL	65	Age 77.4 ± 8.9 years 70.8% NYHA III/IV 97% severe or greater TR TAPSE 14 ± 0.4 mm	86% reduction to moderate or less	• Improvements NYHA class (p < 0.0001). • Improvements 6MWT (p = 0.014). • Improvements KCCQ (p < 0.001). • Right chambers reverse remodelling. • 87.9% freedom from all-cause mortality. • 78.5% freedom from heart failure hospitalization.
TRI.Fr trial[9]: 1-year results 2024	Multicenter, superior, open-label, parallel-group, randomized controlled trial	TriClip	300	Age 78.5 ± 6.3 years 42.5% NYHA III/IV 91% massive/torrential TR TAPSE 18 mm [15-21]	71% reduction to moderate or less TR	• Statistically significant difference in the primary endpoint between T-TEER and GDMT (p < 0.001). • Lower rate of MACE (p = 0.38) and cardiovascular death (p = 0.37) was found in T-TEER group, without statistically significance. • Improvement in KCCQ between T-TEER and GDMT (p < 0.001). • Improvement in patient global assessment between T-TEER and GDMT (p < 0.0001).

Available data regarding T-TEER with TriClip device or PASCAL system. GDMT, guideline-directed medical therapy; KCCQ, Kansas City cardiomyopathy questionnaire; MACE, major adverse cardiovascular event; NYHA, New York Heart Association; sPAP, systolic pulmonary artery pressure; TAPSE, tricuspid annular plane systolic excursion; T-TEER, transcatheter tricuspid edge-to-edge repair; TR, tricuspid regurgitation; 6MWT, 6-Min Walking Test.

associated with a reduced 1-year occurrence of a hierarchical composite primary endpoint—death from any cause or TV surgery, hospitalization for heart failure, and an improvement in quality of life (QoL) as measured with an increase of the Kansas City Cardiomyopathy Questionnaire (KCCQ) $\geq$ 15 points. This was primarily driven by a marked improvement in the QoL. No differences were observed between the groups in terms of mortality and hospitalization rates. Notably, the trial highlighted procedural safety, with >98% of patients who received T-TEER free from major adverse events (cardiovascular death, new-onset kidney failure, endocarditis treated with surgery, and non-elective cardiovascular surgery for a device-related adverse event) and achieved a sustained reduction of TR to moderate or less at 30 days.

Registry and single-arm study's data[4,5,6,7,8] have shown procedural safety and effectiveness of T-TEER, with consistent TR reduction over time, along with clinical improvement (lower post-procedural New York Heart Association [NYHA] functional class, KCCQ and 6-min walking test). Moreover, the capability to achieve significant TR reduction from baseline has been identified as a key predictor of favourable clinical outcomes.

Similarly, the recently published TRI.Fr (Transcatheter Edge-to-Edge Repair for Severe Isolated Tricuspid Regurgitation) trial,[9] randomized 300 patients with severe, symptomatic TR to receive T-TEER plus optimal medical therapy (OMT) or OMT alone. Patients with severe end-organ dysfunction or advanced pulmonary circulation compromise were excluded. The primary

composite endpoint—changes in NYHA functional class, patient-reported global assessment, and major cardiovascular events (death or unplanned heart failure hospitalizations) over 12 months—classified patients as improved, unchanged, or worsened.

T-TEER demonstrated a significant benefit, with 74% of patients achieving improvement in the primary clinical composite endpoint compared to 41% in the OMT group ($P < 0.001$), primarily driven by symptomatic relief. A non-significant trend towards reduced cardiovascular death and heart failure hospitalization was observed, with this reduction being more pronounced than previously observed in other studies, as shown by a 1-year mortality rate of 3.4% in this trial compared to 8.6% in the TRILUMINATE cohort. Additionally, a significant reduction in massive or torrential TR ($P < 0.001$) and a 15-point greater improvement in KCCQ overall summary scores were noted in the T-TEER group. Procedural safety was reaffirmed, with a device success rate of 97.3% and a 30-day major adverse event rate of 0.7%.

This trial confirmed the strong correlation between the reduction of TR severity and improvements in QoL. However, the absence of significant findings in hard endpoint highlights the inherent complexity of TR. In contrast to left-sided heart valve diseases, where early intervention can lead to substantial survival benefits, TR often represents the end stage of a long and chronic disease, in which reversing the clinical trajectory could be particularly challenging. In this context, given the absence of effective pharmacological options and the documented progression of clinical deterioration over time (as observed in the OMT group of the TRI.Fr trial, where the majority of patients worsened within one year), QoL improvement emerges as the most achievable goal in the short-term and should be regarded as a valuable outcome.

Moreover, the development of transcatheter therapies for TR is driving a paradigm shift from a purely palliative approach to one focused on improving symptoms. Moving forward, enrolling patients at earlier disease stages, determining the optimal timing for T-TEER, and ensuring extended follow-up, will be essential for assessing long-term outcomes such as cardiovascular death and heart failure–related hospitalizations.

Who/what

Which valve?

Transoesophageal echocardiography (TOE) is essential for assessing the feasibility of TV repair and, together with fluoroscopy, plays a pivotal role in guiding T-TEER procedures in the cath lab. Consequently, the ability to obtain high-quality TOE images is a critical factor in patient selection for T-TEER. The pre-procedural echocardiographic assessment involves mid-oesophageal (ME), deep-oesophageal (DE), and transgastric (TG) views (*Figure 1*). ME and DE views are necessary for evaluating the regurgitation mechanism, leaflet morphology, the number, direction and localization of regurgitant jets, and the coaptation gaps. TG views, along with a three-dimensional (3D) dataset when available, provide detailed visualization of coaptation gaps, leaflet morphology, scallops, and commissure, through a clear delineation of papillary muscles. In patients with cardiac implantable electronic devices, TG imaging is particularly valuable for visualizing the lead trajectory and its interactions with the valve leaflets. This comprehensive imaging strategy allows for the classification of TR into groups of increasing anatomical complexity, highlighting the necessity for referral to high-volume centres and/or consideration of alternative transcatheter therapies (*Figure 2A*).

Moreover, it is important to note that patients with TR are often referred with an already established significant volume overload. This exacerbates right-sided chamber distortion, further annular dilatation, and leaflet tethering, leading to severe TR with large coaptation gaps that may be unsuitable for T-TEER. In this context, diuretic therapy may optimize volume status and reduce coaptation gaps and leaflet tethering, potentially enabling previously unfeasible interventional procedures.[10]

Which right ventricle and pulmonary hypertension?

Comprehensive evaluation of the RV and pulmonary circulation is a fundamental step for pre-procedural patients' selection (*Figure 2B*) and should be conducted in a euvolemic state. This includes a multimodality imaging approach with monodimensional (M-mode), two-dimensional (2D), and 3D transthoracic echocardiography (TTE) for assessing RV size and function, and cardiac magnetic resonance or computed tomography as the gold standard for chamber quantification. Right heart catheterization (RHC) remains the reference method for pulmonary circulation. For the assessment of RV dysfunction, the common TTE parameters include RV fractional area change <35%, tricuspid annular plane systolic excursion (TAPSE) < 17 mm, systolic myocardial velocity <9.5 cm/s, free-wall longitudinal strain <20%,[11] and 3D RV ejection fraction (RVEF) < 45%. Among these, 2D-derived measures, 3D RVEF, and CMR RVEF are less load-dependent and provide superior prognostic value.

However, the chronic volume overload associated with severe TR may impair the accurate estimation of RV contractile function with standard parameters. Therefore, should we consider the presence of RV contractile reserve through stress imaging as a more reliable measure? This approach could serve as a prognostic tool and offer insight into potential RV functional improvement following effective TR reduction via T-TEER, optimizing patient selection and predicting post-procedural outcomes.

It is also essential to evaluate the relationship between RV contractility and the afterload of the pulmonary circulation, known as right ventricular–arterial coupling. The TAPSE/systolic pulmonary artery pressure (sPAP) ratio is the most extensively studied non-invasive measure of this coupling and has demonstrated prognostic value in patients with severe TR undergoing T-TEER.[12]

However, the echocardiographic estimation of sPAP in severe TR requires careful interpretation. In advanced cases, the rapid equalization of atrial and ventricular pressures often reduces the peak TR velocity, resulting in an underestimation of sPAP. Consequently, RHC remains

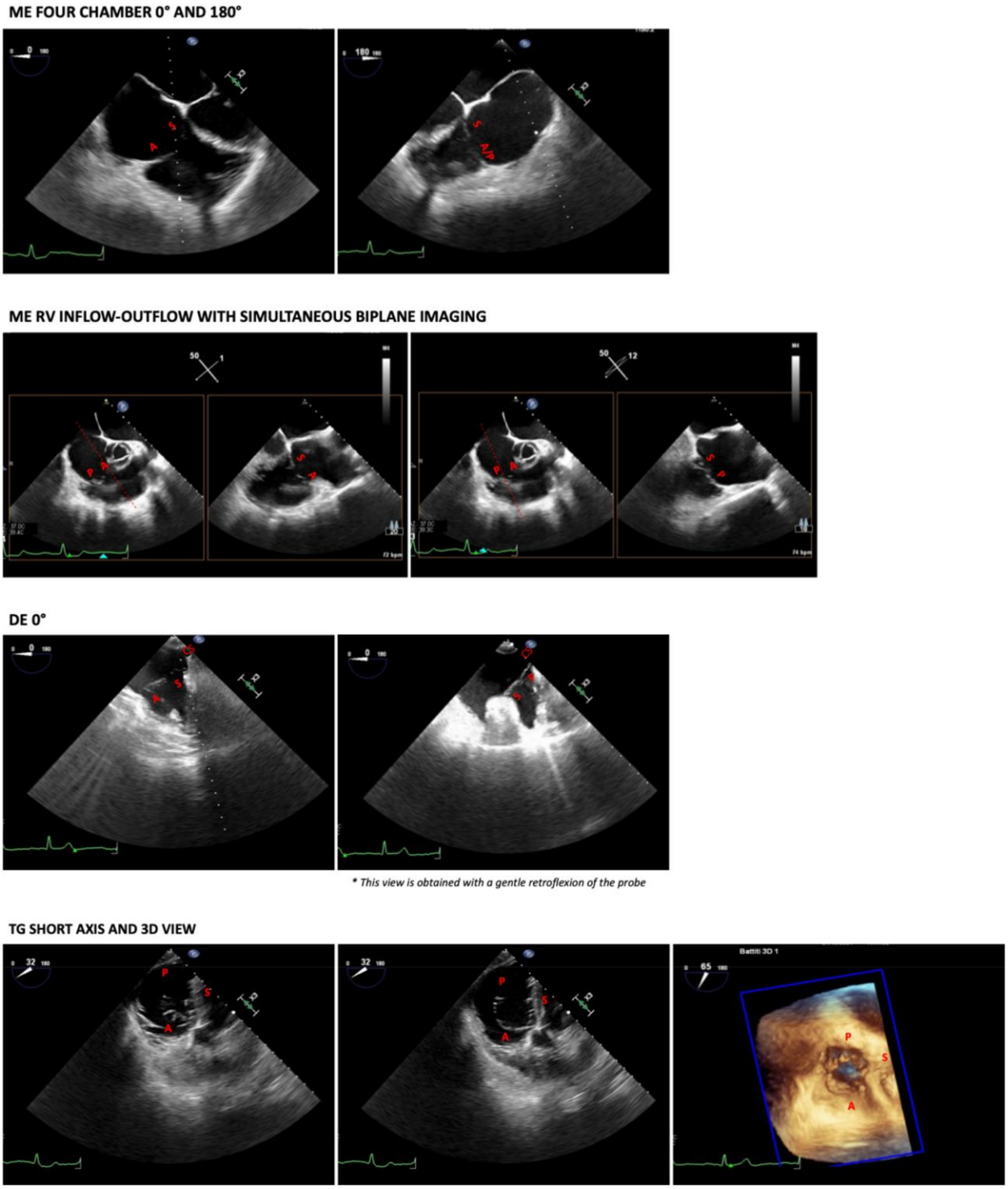

Figure 1 Echocardiographic assessment of the tricuspid valve. Main TOE views for tricuspid valve assessment. A, anterior leaflet; P, posterior leaflet; S, septal leaflet; CS, coronary sinus. DE, deep-oesophageal; ME, mid-oesophageal; RV, right ventricle; TG, transgastric; 3D, tridimensional.

indispensable for an accurate assessment of right heart physiology. RHC provides essential haemodynamic data regarding the severity and mechanism of pulmonary hypertension (PH), pulmonary vascular resistance (PVR), and RV function. Specifically, pulmonary artery pressure, transpulmonary gradient, PVR, and RV stroke work have been identified as predictors of adverse outcomes in patients undergoing T-TEER.[13] The same study indicates that patients with predominant post-capillary PH derive greater benefit from T-TEER compared to those with predominant pre-capillary PH. The latter group is associated with a higher mortality risk, likely attributable to the progression of the underlying disease process.[13] In the context of combined post-capillary PH,

A VALVE ANATOMY

Favourable	Feasible	Unfavourable
• Coaptation gap ≤7 mm • Central jet extending in the anteroseptal commissure • Small prolapse/flail	• Coaptation gap >7 but ≤8.5 mm • Central jet extending in the posteroseptal commissure • Wide prolapse/flail	• Coaptation gap >8.5 mm • Anteroposterior or non-central/eccentric jet • Multiple prolapse/flails without target lesion • Extreme tethering (particularly for septal leaflet)
• Trileaflet morphology	• Non-trileaflet morphology	• Leaflet morphologic deterioration (thickening/shortening/perforation)
• No CIED RV lead	• CIED RV lead without leaflet impingement	• CIED RV lead with leaflet impingement
• Favourable angle of approach • Good TOE windows	• Feasible angle of approach • Sufficient TOE windows	• Unfavourable angle of approach • Poor TOE windows

B RIGHT VENTRICLE AND PULMONARY HYPERTENSION

Favourable	Feasible	Unfavourable
• Normal to mildly reduced RV function • Normal to mild RV dilatation	• Moderately or severely reduced RV function • Moderate or severe RV dilatation attributable to volume overload	• Severely reduced RV function • Severe RV dilatation not primarily attributable to volume overload
• No PH	• Isolated post-capillary PH or combined post-capillary PH with reversibility profile at sodium nitroprusside administration	• Pre-capillary PH or severe combined prost-capillary PH without reversibility profile at sodium nitroprusside administration

C PATIENT

Favourable	Feasible	Unfavourable
• Normal renal function • Normal liver function • No pulmonary fibrosis or restrictive/obstructive pulmonary disease • Capability to perform daily activities	• Moderately impaired renal function • Moderately impaired liver function • Mild to moderate pulmonary fibrosis or restrictive/obstructive pulmonary disease • Impaired capability to perform daily activities	• Severely impaired renal function • Severely impaired liver function • Severe pulmonary fibrosis or restrictive/obstructive pulmonary disease • Need for assistance in daily activities and self-care

Figure 2 Pre-procedural selection for T-TEER. Favourable, feasible, and unfavourable criteria according to tricuspid valve anatomy (2A), right ventricular function and pulmonary hypertension (2B), and overall clinical status (2C). CIED, cardiac implantable electronic devices; PH, pulmonary hypertension; RV, right ventricle; sPAP, systolic pulmonary artery pressure; TOE, transoesophageal echocardiography.

determining the relative contribution of the pre-capillary component can be challenging. Assessing PVR reversibility with sodium nitroprusside could provide valuable insights into the potential clinical and prognostic benefits of T-TEER in this subgroup.

Which patient?

In addition to evaluating anatomical characteristics of TV, right heart function and pulmonary circulation, various other parameters have been identified to enhance patient stratification (*Figure 2C*). While scores like the STS and TRI-SCORE[14] have been developed for estimating the risk of in-hospital mortality in patients with severe TR undergoing isolated tricuspid valve surgery, no scoring systems have been specifically created to assess the risk of adverse outcomes in patients undergoing T-TEER.

Even more than in patient selection within the broader context of structural cardiology, it is crucial to consider advanced end-organ damage, such as terminal renal

failure, manifest liver cirrhosis, or severe pulmonary fibrosis/obstructive lung disease, life expectancy, and the patient's ability to perform daily activities and self-care. In this regard, a new clinical and functional classification has recently been proposed, incorporating episodes of right heart failure, symptoms, end-organ involvement, and daily dose of diuretic therapy.[15]

How?

T-TEER is performed under general anaesthesia with TOE guidance or, less frequently, intracardiac echocardiography. Currently available devices are the TriClip™ and the PASCAL™ (Edwards Lifesciences, Irvine, CA, USA) systems. Initially, T-TEER procedures were carried out with the *off-label* use of the MitraClip™ device (Abbott Vascular, Santa Clara, CA, USA), but the lack of interatrial septum support and the complex trajectory resulting from the angle between the inferior vena cava and the tricuspid plane were major issues. A dedicated T-TEER device, the TriClip™, was therefore developed, incorporating a shorter curved guiding catheter, an additional steerable plane of motion, and advanced clip technology with longer arms and independent gripper activation. The PASCAL™ system includes a central spacer designed to fill the coaptation gap, with adjacent paddles and clasps that anchor the implant to the native leaflets, either simultaneously or independently.

TOE guidance is essential during the entire procedure. Initial placement of the guidewire and delivery system within the right atrium is typically performed using ME bi-caval or four-chamber views, with simultaneous biplane imaging. Once the clip is positioned within the right atrium, ME RV inflow–outflow views with biplane imaging optimize visualization of leaflet alignment, clip trajectory, and target zone. During clip rotation, TG short axis provides a full view of three tricuspid leaflets. Correct alignment with the coaptation line is confirmed using ME RV inflow–outflow views, where properly aligned clips will have invisible open arms. Similarly, during the grasping phase, these views are used to monitor the interaction between the clip arms and the leaflets. Before deployment, it is essential to confirm adequate leaflet grasping with multiple echocardiographic views. Finally, following clip release, a thorough assessment of the tricuspid inflow gradient and the reduction in TR must be performed to evaluate procedural success and guide further management.

The selection of implantation techniques—zipping (with clips placed along the anteroseptal commissure towards the valve centre) or clover (with clips positioned in the anteroseptal and posteroseptal commissures)—depends on the number and location of regurgitant jets. In both strategies, the septal leaflet is always involved due to its anatomical proximity to the interventricular septum. The anteroseptal commissure is generally targeted first, as it offers optimal visualization via TOE and is near the larger anterior leaflet. Moreover, targeting the posteroseptal commissure initially can cause an ultrasound shadow, complicating further clip placement. Careful positioning of clips is required to avoid excessive proximity to commissures, as these areas, rich in papillary muscle attachments, pose challenges and increase the risk of device entrapment. Additionally, anatomical variability, such as the presence of scallops, pacemaker leads, and embryonic remnants, must be thoroughly assessed.

When?

A crucial question to address is: can the knowledge acquired from mitral valve disease be applied to TV? Probably not. First, none of the disease-modifying pharmacological or device-based therapies currently validated for left ventricular dysfunction have demonstrated efficacy in managing RV heart failure. Second, the natural history of TR is considerably longer and more insidious, with a greater impact on systemic congestion. Consequently, patients are often present at advanced stages of the disease, typically burdened by more severe comorbidities. Additionally, the assessment of right-sided heart structures is more complex, frequently requiring multimodality approach, and is far more load-dependent compared to the left-sided counterpart. Finally, the existing literature and overall culture regarding TR remain less extensive and mature compared to those addressing mitral regurgitation.

From a pathophysiological perspective, untreated TR leads to a vicious cycle characterized by progressive RV dilation and worsening regurgitation severity. While early RV remodelling may occur with preserved function, chronic TR ultimately drives maladaptive changes in RV geometry, including papillary muscle displacement, annular enlargement, and leaflet tethering. These alterations result in torrential TR and advanced RV dysfunction, ultimately leading to increased morbidity and mortality, even after T-TEER. Early interruption of this pathological cycle might be essential to improve the long-term prognosis of patients with TR. Undoubtedly, patient's volume loading should be minimized; in this view, red-blood-cell transfusion should be restricted to cases with severe anaemia, given its liberal use is associated with early mortality, as already documented in patients undergoing other structural interventions.[16]

Although the precise timing for T-TEER has not yet been established, it seems reasonable to refer any symptomatic patient with severe TR to a dedicated heart team comprising cardiac surgeons, interventional cardiologists, and imaging specialists, with a focus on preventing irreversible right heart remodelling, PH, and end-organ failure.

The timing of T-TEER should consider several factors, including the patient's clinical profile, disease severity, and the concomitant organ function. Patients with preserved RV function, absence of PH, and no signs of organ dysfunction are likely to derive the greatest benefit from TV intervention, if performed as soon as possible. Conversely, in patients with severe RV dysfunction without contractile reserve, pre-capillary or severe combined post-capillary PH, end-stage organ failure, and significant impairment in daily activities and self-care, the procedure may be futile. Careful evaluation in the heart team of patients in the grey zone is essential to balance the benefits of TR reduction. In this scenario, advanced assessments, such as evaluating RV contractile reserve with physical or pharmacological stress TTE/CMR

and assessing PVR reversibility with sodium nitroprusside, may provide valuable insights for T-TEER eligibility.

Conclusion

A comprehensive pre-procedural assessment of TV anatomy, RV function, PH, and overall clinical status is essential to select suitable patients and determine the optimal timing for T-TEER. Although T-TEER is rapidly emerging in response to a previously unmet clinical need, its long-term impact on cardiovascular mortality and heart failure-related hospitalizations requires further validation through randomized trials and extended follow-up studies.

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