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*JACC* STATE-OF-THE-ART REVIEW

# Transcatheter Tricuspid Valve Replacement

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## ABSTRACT

Transcatheter tricuspid valve replacement (TTVR) has emerged as a promising intervention for the treatment of severe tricuspid regurgitation with complex valve morphology. This consensus document provides a comprehensive overview of the current state of orthotopic TTVR, focusing on patient selection, procedural details, and follow-up care. Clinical outcomes from initial studies and compassionate use cases are discussed, highlighting the effectiveness of TTVR in reducing tricuspid regurgitation, inducing reverse right ventricular remodeling, and enhancing patients' quality of life. This review paper also addresses potential complications and challenges associated with TTVR, such as new-onset conduction disturbances, bleeding complications, and afterload mismatch, and provides expert recommendations for the periprocedural management, anticoagulation strategies, and long-term follow-up. With the commercial approval of the first TTVR system in the United States and Europe, it intends to serve as a reference for clinicians and researchers involved in the evolving field of transcatheter tricuspid valve interventions. (JACC. 2025;85:265-291)


Tricuspid regurgitation (TR) is an independent predictor of morbidity and mortality in various populations, including patients with left heart failure with preserved (HFpEF) or reduced left ventricular function (HFrEF),[1-3] multivalvular disease,[4,5] and after cardiac implantable electronic devices (CIED) lead implantation.[6-8] The cumulative mortality of untreated severe TR of any etiologies reaches ~30%, ~50%, and ~70% at 1-, 2-, and 4-year follow-up, respectively,[9] and its prevalence

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**ABBREVIATIONS AND ACRONYMS**

**AF** = atrial fibrillation

**CIED** = cardiac implantable electronic device

**CT** = computed tomography

**DOAC** = direct oral anticoagulant

**HFH** = heart failure hospitalization

**HFpEF** = heart failure with preserved ejection fraction

**HFrEF** = heart failure with reduced ejection fraction

**ICE** = intracardiac echocardiography

**IVC** = inferior vena cava

**MV** = mitral valve

**NOCD** = new-onset conduction disturbances

**OAC** = oral anticoagulation

**OMT** = optimal medical treatment

**PH** = pulmonary hypertension

**PVR** = pulmonary vascular resistance

**RA** = right atrial

**RHC** = right heart catheterization

**RV** = right ventricle/ventricular

**RVEF** = right ventricular ejection fraction

**sPAP** = systolic pulmonary artery pressure

**TAPSE** = tricuspid annular plane systolic excursion

**TEE** = transesophageal echocardiogram

**TR** = tricuspid regurgitation

**TTE** = transthoracic echocardiography

**T-TEER** = transcatheter tricuspid valve edge-to-edge repair

**TTVR** = transcatheter tricuspid valve replacement

**TV** = tricuspid valve

**VKA** = vitamin K antagonist

increases with age (up to 4.0% beyond the age of 75 years).[10,11]

Although tricuspid transcatheter edge-to-edge repair (T-TEER) has emerged as a safe treatment to reduce TR and improve quality of life,[12-14] the procedure is limited to individuals with suitable anatomy and sufficient imaging quality using transesophageal echocardiography (TEE).[15] Patients with complex anatomy and advanced disease stages (large tricuspid annular dimensions or coaptation gaps, excessive leaflet tethering, lead-induced TR) may require orthotopic transcatheter tricuspid valve replacement (TTVR) to achieve optimal TR reduction[16] that has been associated with symptomatic and prognostic improvement, right ventricular (RV) reverse remodeling,[17,18] and improvement in organ function.[19,20] Conversely, elimination of TR by TTVR may have adverse effects, including atrioventricular conduction disturbances or afterload mismatch with acute RV failure.[19,21] The field of TTVR is rapidly evolving with a growing evidence base. The first device has already received CE and U.S. Food and Drug Administration (FDA) approval with commercial cases being performed.

This document summarizes the current knowledge regarding orthotopic TTVR focusing on diagnostic work-up, TTVR indications and patient selection, as well as periprocedural management and follow-up. The proposed recommendations are based on a consensus among expert authors representing centers with large TTVR experience. Summary sections are provided at the end of each chapter to allow for a rapid and synthetic overview of the main messages.

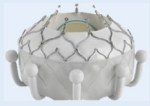
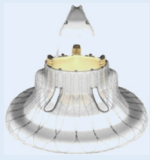
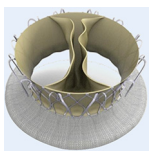
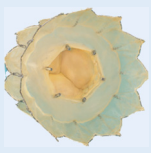
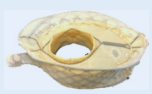
## TTVR SYSTEMS

TTVR systems differ greatly in terms of valve design, stent frame, anchoring mechanism, available valve sizes, and delivery systems (French size, access site, number of catheters, and release mechanisms) (**Table 1**). Early TTVR systems were initially designed for the mitral valve (MV) and simply used in the tricuspid position. Important distinctions between the MV and the TV in the context of transcatheter interventions include the following: 1) proximity to the atrioventricular node and conduction system and potential direct impact of valve implantation on the RV function; 2) lower systolic closing pressure decreasing the risk of valve embolization, endomyocardial erosion, and migration; 3) larger, noncalcified native TV annulus; and 4) challenging access and deliverability caused by the frequent angulation between the inferior vena cava (IVC) and the TV annulus (referred to as *"IVC offset"*). Both the large size of the TV and the lower opening and closing forces of the valve increase the risk of thrombosis.

Currently used anchoring mechanisms can be categorized into 4 types: 1) multiple subannular anchors that engage the subvalvular apparatus and the leaflets (eg, Evoque, Cardiovalve, Trisol, MonarQ); 2) annular anchoring using radial strength and leaflet tines (eg, Intrepid, Topaz); 3) intraventricular septal anchor combined with subleaflet anchoring (LuxValve); and 4) radial strength and RVOT anchoring (Vdyne). The mechanism of anchoring may affect TR reduction and the occurrence of conduction disturbances and has important consequences for imaging requirements during the procedure. Valve designs with subannular anchors require detailed intraprocedural imaging to ensure correct position below the annulus/leaflet, whereas confirmation of a coaxial trajectory may suffice for devices relying on radial strength. Second-generation systems are expected to better adapt to the above-mentioned TV specificities, while also allowing for optimized interaction with preexisting CIED, as well as recapturability.

TTVR systems are delivered either via the transfemoral or transjugular venous access. Compared to transfemoral, the transjugular route has the advantages of a shorter and less tortuous access to the right atrium (RA), as well as less offset between the superior caval vein and the center of the tricuspid annulus, whereas the potential disadvantages mainly include less radiation protection and unfamiliarity in catheter handling from the neck. In both cases, a fully percutaneous technique should be the goal to avoid vascular and bleeding complications. A second degree of catheter steerability or, alternatively, 2 independent catheters are preferred to facilitate delivery via the transfemoral access, when the IVC has a significant offset from the tricuspid annulus. Finally, the valve design may also affect long-term durability and lifetime management. Because large valves need to be designed to accommodate the relatively large tricuspid annulus, alternative concepts consist of either a double-stent (outer frame for anchoring and inner frame supporting the valve leaflets) or a single frame with large leaflets. Large leaflets are particularly exposed to increased shear stress with a theoretically higher risk of thrombosis and degeneration, whereas

**TABLE 1 Characteristics of the Main Transcatheter Tricuspid Valve Replacement Devices**

| Device | Access | Delivery System | Anchoring Mechanism | Valve Sizes |
|---|---|---|---|---|
| Evoque (Edwards Lifesciences)  | Transfemoral | 28-F | Intra-annular skirt, Leaflets anchors | 44,[a] 48,[a] 52,[a] and 56 mm |
| Intrepid (Medtronic)  | Transfemoral | 35-F (29-F under development) | Radial force, Leaflet tines | 42 and 48 mm |
| Lux-Valve Plus (Jenscare)  | (Transatrial or) Transjugular | 33-F | Anterior and posterior leaflet grasping, septal anchor | 40, 45, 50, 55, 60, 65, and 70 mm |
| Trisol (Trisol Medical)  | Transjugular | 30-F | Axial force, Leaflet anchors | 1 size (40-53 mm) |
| Topaz (TRiCares)  | Transfemoral | 29-F | Subannular anchors | 45 and 55 mm |
| Cardiovalve (Cardiovalve)  | Transfemoral | 32-F | Leaflet grasping, Atrial flange | M, L, and XL |
| VDyne (VDyne)  | Transfemoral | 28-F | RVOT and posteroseptal tab, proximal loop (ventricular perimeter reduction), cuff shape, oversizing | 5 sizes (42 to 56 mm) |
| MonarQ (InQB8 Medical Technologies)  | Transjugular | 29-F | Leaflet pinching using atrial and ventricular arms | 2 sizes (52 and 56 mm) |

[a]Commercially available.

RVOT = right ventricular outflow tract.

double-frame valves hypothetically allow future valve-in-valve implantation with commercially available balloon-expandable valves. **Figure 1** shows step-by-step intraprocedural fluoroscopic imaging of 4 currently used TTVR devices (**Figures 1A to 1E**, EVOQUE; **Figures 1F to 1J**, LuX-Valve Plus; **Figures 1K to 1O**, Topaz Valve; and **Figures 1P to 1T**, Cardiovalve).

## EVIDENCE ON TTVR

Clinical, functional, and echocardiographic outcomes of orthotopic TTVR systems with evidence from prospectively registered studies, first-in-human reports, compassionate use series, and 1 randomized clinical trial are summarized in **Table 2**. To date, TTVR systems have been investigated in elderly (mean age 70-80 years), highly symptomatic (NYHA functional class III/IV 75%-100%) patients at increased surgical risk (mean STS/EuroScore II: 7%-11%) with predominantly severe to torrential TR and with high prevalence of atrial fibrillation (AF >85%) and renal impairment (>50%). The eligibility/ineligibility for T-TEER has been reported in few studies, but was not considered as an inclusion/exclusion criteria in the majority of them.

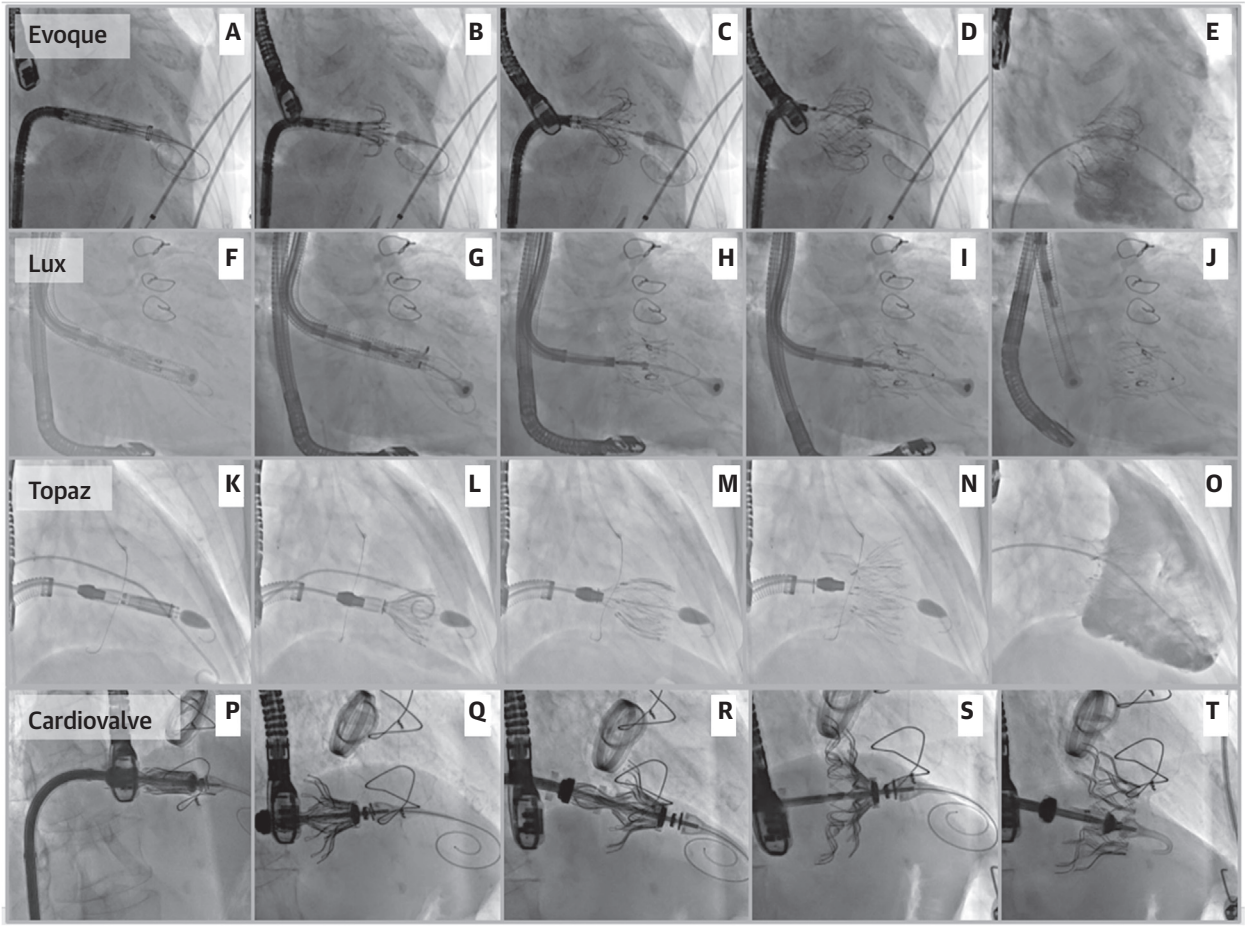
Historically, the GATE system (NaviGATE Cardiac Structures Inc) was the first TTVR system that was implanted mainly using direct transatrial or transjugular access. A preliminary study among 30 patients with severe TR reported device success in 87% and ≤ mild TR in 76% of patients, but a high in-hospital mortality of 10% and conversions to surgical intervention in 5% of the patients.[22]

The largest clinical experience to date has been compiled with the Evoque TTVR system, which is the first TTVR device approved for clinical use (CE and FDA approval). Following favorable results in a compassionate use series (n = 38) and first-in-human study (n = 27),[23] the safety and performance of the Evoque system was prospectively investigated in the multicenter, single-arm TRISCEND study (NCT04221490) (**Table 2**, **Figures 2 and 3**).[24] Among 176 patients with symptomatic ≥ moderate TR (severe in 88%), device and procedure success were high (94% and 93%, respectively) and achieved within a short intervention time (mean 72 ± 31 minutes). A new permanent pacemaker implantation was required in 13.3% of patients. The prespecified safety composite major adverse event endpoint at 30 days was observed in 18.6% of patients (CV death 1.7%, severe bleeding 16.9%), and all-cause mortality and heart failure hospitalizations (HFHs) at 1 year in 9.4% and 10.2% of patients, respectively. In paired echocardiographic analyses, TR was reduced to mild or none/trace in 98.7% of patients at discharge, changes that were maintained at all follow-up points throughout 1 year. Parameters of RV systolic function including fractional area change and tricuspid annular plane systolic excursion (TAPSE) numerically decreased, whereas cardiac output and stroke volume increased accompanied by decreased mean RA and pulmonary artery pressures. At 1 year, the functional status markedly improved with most patients experiencing no or mild heart failure symptoms (93.3%, NYHA functional class I or II) associated with large improvements in measures of quality of life (25.7-point increase in Kansas City Cardiomyopathy Questionnaire [KCCQ]). The favorable echocardiographic, functional, and clinical outcomes were largely maintained throughout 2-year follow-up (**Table 2**), which was also confirmed in a multicenter report of 38 patients treated with the Evoque system under compassionate use conditions.[25]

The TRISCEND II trial (NCT04482062) is the first randomized trial comparing TTVR to optimal medical therapy (OMT) using a 2:1 randomization among 400 enrolled patients with severe TR (**Figure 2**).[26] The hierarchical composite primary endpoint consisted of all-cause mortality, RV assist device implantation or heart transplantation, TV intervention, annualized rate of HFH, and improvements in KCCQ ≥10 points, NYHA ≥1 functional class, and 6-minute walk distance ≥30 m at 1-year follow-up. Predominantly driven by improvement in KCCQ and NYHA functional class, the win-ratio of 2.02 for the primary endpoint favored TTVR plus OMT over OMT alone. The 1-year Kaplan-Meier estimates for all-cause mortality were 12.6% ± 2.1% (TTVR + OMT) and 15.2% ± 3.3% (OMT) and for HFH 20.9% ± 2.6% and 26.1% ± 4.1%, respectively. TR reduction to ≤ mild was observed in 95.3% and 2.3% of patients randomized to TTVR plus OMT and OMT, respectively. Major adverse events in the TTVR cohort included a 3.5% mortality rate, 10.4% severe bleeding complications, and 24.7% CIED implantation in pacemaker-naive patients at 30 days.

Preliminary evidence has also been obtained with the second-generation LuX-Valve Plus system (Jenscare Biotechnology Co) that is implanted via the right transjugular route. A first-in-human report in 10 patients observed device success in 100%, need for pacemaker in 10% without other adverse clinical events during 30-day follow-up [27,28] (**Table 2**). The 1-month outcomes of the 96 patients enrolled into the TRAVEL II (Transcatheter Right Atrial-ventricular Valve rEplacement With LuX-Valve Via Jugular

**FIGURE 1** Intraprocedural Fluoroscopic Imaging of 4 Transcatheter Tricuspid Valve Replacement Devices




Step-by-step intraprocedural fluoroscopic imaging of 4 transcatheter tricuspid valve replacement devices (A to E: EVOQUE; F to J: Lux-Valve; K to O: Topaz Valve; P to T: Cardiovalve).

Vein) study (NCT05194423) using the LuX-Valve system via the transjugular route reported device success in 97% and a composite of death (1%), MI (0%), stroke (0%), severe paravalvular leak (1%), and new-onset atrioventricular block requiring pacemaker implantation (2%) in a total of 6.5% of patients (Table 2).

Results of the Cardiovalve TTVR system (VENUS Medtech) have been reported in 20 compassionate use patients with severe TR[29] (Table 2). Device success was achieved in 90% of cases, with 1 patient requiring conversion to surgical valve intervention because of valve canting and 1 patient requiring surgical removal of the delivery system from the iliac vein. At 30-day follow-up, TR was reduced to ≤mild in 95% of patients and mortality amounted to 10%. In addition, proof of concept has been established in small series of compassionate use cases for the VDyne[30] and MonarQ valves.[31]

## DIAGNOSTIC WORK-UP AND PROCEDURAL IMAGING

**GENERAL CONSIDERATIONS.** Patients presenting with severe, symptomatic TR should first receive optimal medical management. Guidelines recommend diuretic agents to treat congestive symptoms associated with right heart failure, as well as initiation of therapies to treat the primary cause of heart failure (eg, guideline-directed medical therapy for HFrEF or rhythm control of AF, pulmonary vasodilators in the setting of precapillary pulmonary

**TABLE 2 Published Evidence Regarding Currently Available TTVR Systems**

| Device | Study Name (Identifier) | N (Study Sites) | Age, y | Female, % | STS-PROM | NYHA Functional Class III/IV | Renal Insufficiency, % | AF/AFL, % | PPM/ICD, % | Ascites, % | TR > Severe, % | TR Etiology, % |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| EVOQUE | First-in-man study[b] (NA) | 27 (7) | 77 ± 8 | 89 | 8.6 ± 5.5 | 89 | 56 | 85 | 33 | 54 | 81 | Functional 70<br>Degenerative 11<br>Mixed 19 |
| | Compassionate use[c] (NA) | 38 (8) | 77 ± 12 | 74 | 7.9 ± 6.5[a] | NA | NA | NA | NA | NA | 89 | NA |
| | TRISCEND (NCT04221490) | | | | | | | | | | | |
| | 1-y report[d] | 176 (29) | 79 ± 7 | 71% | 7.4 ± 5.8 (MV repair)<br>10.0 ± 5.3 (MV replacement) | 75 | 59 | 92 | 32 | 22 | 43 | Primary 10%<br>Secondary 68%<br>Mixed 14%<br>CIED 3%<br>Indeterminate 5% |
| | 2-y report[e] | 208 (29) | 79 ± 7 | 71% | 10.0 ± 5.4 (MV replacement) | 73 | 62 | 90 | 33 | 20 | 48 | Functional/mixed 84.1%<br>Degenerative 8.2%<br>Other 7.7% |
| | TRISCEND II[f] (only EVOQUE arm is reported) (NCT04482062) | 400 (45) | 79.2 | 75.5 | 9.7% (MV replacement) | 70.3 | 54.5 | 93 | 38 | 19.3 | 55 | Primary 14.3<br>Secondary 71.8<br>Mixed 9.3<br>Indeterminate 2.8 |
| CardioValve | Compassionate use[g] (NA) | 20 (9) | 79 ± 6 | 50 | 6.2 ± 3.9 | 60 | NA | NA | NA | NA | 90 | Functional 100 |
| LuX-Valve Plus | First-in-man study[h] (NA) | 10 (1) | 70 | 70 | EuroScore II 11 ± 1 | 100 | NA | 40 | 10 | NA | 100 | NA |
| | TRAVEL II[i] (NCT05194423) | 96 (15) | 71 ± 8.8 | 71.9 | 9.1 ± 4.1 (MV replacement) | 100 | NA | 83.5 | 17.5 | 8.9 | 61.4 | Secondary 86<br>Primary 14 |
| Topaz | Early compassionate use and special access experience[j] (NA) | 11 (NA) | NA | NA | NA | 100 | NA | NA | NA | NA | 54 | NA |

[a]Patients without a preexisting pacemaker. Data are obtained from published papers or oral presentations. [b]Webb et al.[23] [c]Stolz et al.[25] [d]Kodali et al.[56] [e]Makkar London Valves 2023.[90] [f]Hahn[26] [g]Fam et al.[29] [h]Zhang et al.[27] [i]Ge TCT 2023.[91] [j]Ong TCT 2022.[92]

AF = atrial fibrillation; AFL = atrial flutter; CIED = cardiac implantable electronic device; CV = cardiovascular; HF = heart failure; MAE = major adverse event; MI = myocardial infarction; PPMI = permanent pacemaker implantation; TR = tricuspid regurgitation.

*Continued on the next page*

hypertension [PH]).[32] OMT, however, continues to evolve as more is learned about the relationship between TR and management of heart failure.[33] TR reduction is observed following reduction of mitral regurgitation,[34] after cardiac resynchronization therapy,[35] and rhythm control management.[36] More recently, HFpEF has been associated with atrial secondary TR[37,38] and initiation of medical therapy for this condition may also improve TR. Randomized controlled trials assessing the effect of sodium glucose cotransporter-2 inhibitors on TR, are underway (NCT06027307 and NCT05686616). Because of this rapidly evolving medical landscape, the multidisciplinary Heart Team should include heart failure experts who may optimize medical therapy according to the most recent trials and guideline recommendations before consideration of interventional therapy.

**IMAGING EVALUATION.** The diagnostic imaging work-up of patients considered for TTVR should be ideally performed in an euvolemic and compensated state and preferably while the patient is on a stable diuretic regimen because RV function and size are sensitive to changes in preload conditions. Imaging in a volume overloaded condition may lead to unjustified TTVR exclusion or excessive valve oversizing after optimization, while excessive volume depletion may result in valve undersizing and instability. It is therefore recommended to document the patient's weight at the time of screening and to compare it with the one recorded at procedure admission. Although transthoracic echocardiography (TTE) remains the primary tool for screening, TR grading and evaluation of the RV function often require the use of advanced multimodality imaging.

**TRANSTHORACIC AND TRANSESOPHAGEAL ECHOCARDIOGRAMS.** A careful assessment and quantification of left-sided or pulmonary vascular pathologies, which may contribute to tricuspid

**TABLE 2 Continued**

| Device | Study Name (Identifier) | Procedural Success, % | Device Time | F/U | Death, % | CV death, % | Major Structural Complications, % | Renal Replacement Therapy, % | Unplanned TV Reintervention, % | Major Access Site Complications, % | Severe Bleeding, % | HF Hospitalization, % | PPMI,[a] % |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| EVOQUE | First-in-man study[b] (NA) | 92 | 68 ± 47 min | 30 d | 0 | 0 | NA | 4 | 0 | NA | 11 | 0 | 7 |
| | | | | 1 y | 7 | 0 | NA | 7 | 0 | NA | 15 | 7 | 11 |
| | Compassionate use[c] (NA) | NA | NA | 1 y | 14 | NA | NA | NA | 2.6 | NA | 10.5 | NA | 10.5 |
| | | | | 2 y | 29 | NA | | | | | | | |
| | TRISCEND (NCT04221490) | | | | | | | | | | | | |
| | 1-y report[d] | 93.0 | 71.6 ± 31.4 min | 30 d | 2.3 | 1.7 | 1.7 | 2.3 | 2.3 | 16.9 | 2.9 | 13.3 | 0.6 |
| | | | | 1 y | 9.9 | 9.4 | 3.4 | 4.0 | 2.7 | 25.5 | 11.6 | 13.3 | 1.3 |
| | 2-y report[e] | NA | 63.0 (48.0-83.0) min | 2 y | NA | 16.3 | 0.7 | 3.5 | 4.3 | 3.5 | 30.5 | 15.2 | 13.4 |
| | TRISCEND II[f] (only EVOQUE arm is reported) (NCT04482062) | | | | | | | | | | | | |
| | | NA | 56.5 (41.0-75.0) min | 1 y | 11.6 | 8.5 | 1.2 | 3.1 | 0.8 | 3.1 | 15.4 | 20.9 ± 2.6 | 27.8 |
| | | NA | NA | 1 y | 10.5 | 7.5 | 0 | NA | 3.0 | NA | 5.3 | 26.1 ± 4.1 | 3.8 |
| CardioValve | Compassionate use[g] (NA) | 90 | NA | 30 d | 10 | NA | 0 | NA | 10 | NA | 20 | 5 | 10 |
| LuX-Valve Plus | First-in-man study[h] (NA) | 100 | NA | 30 d | 0 | 0 | 0 | NA | 0 | NA | 0 | 0 | 10 |
| | TRAVEL II[i] (NCT05194423) | 96.8 | 35.6 ± 20.8 min | 30 d | 1.1 | NA | 0 | 1.1 | 1.1 | 0 | 0 | NA | 2.2 |
| Topaz | Early compassionate use and special access experience[j] (NA) | NA | 26 ± 10 min | 30 d | 9.1 | NA | NA | 0 | 36.4 | NA | NA | 0 | 0 |

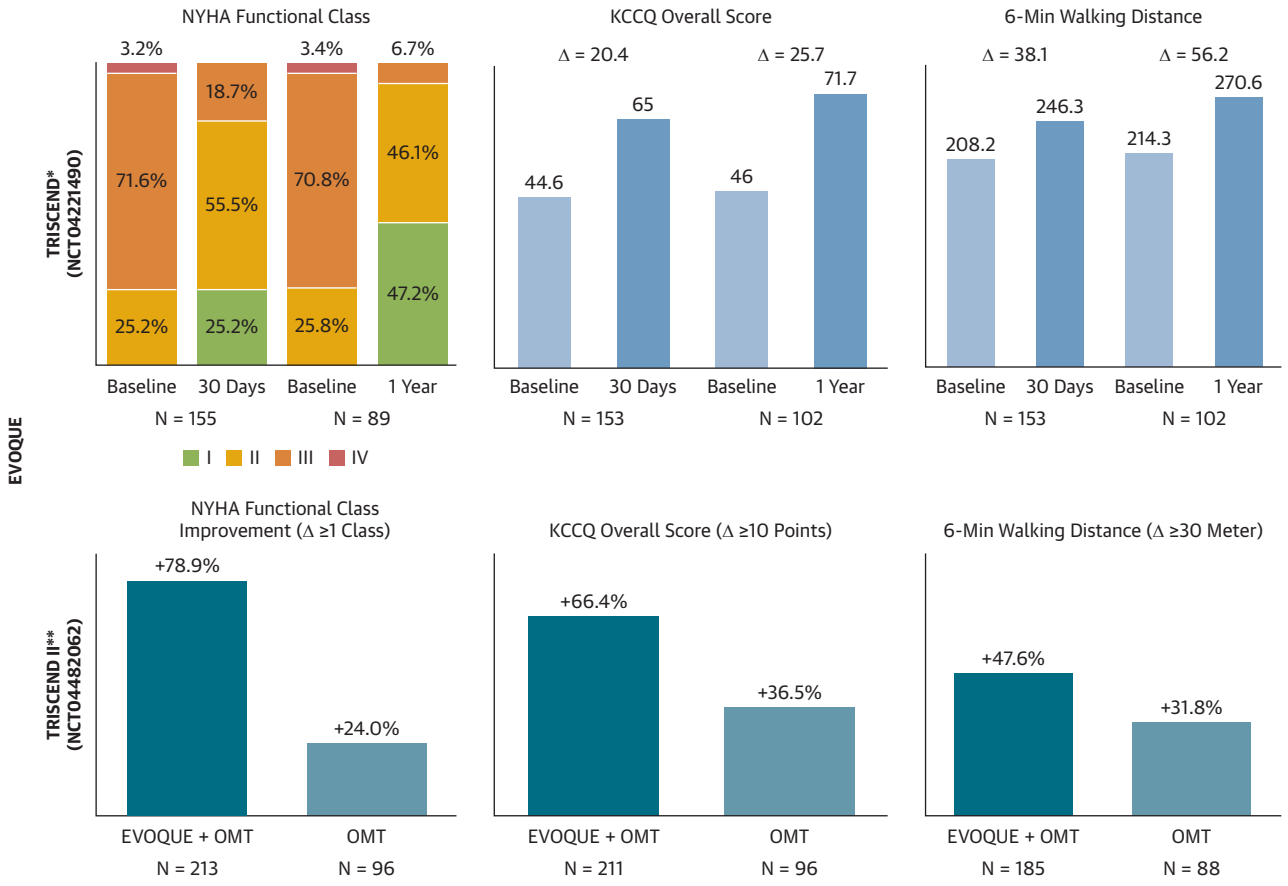
disease, should always be performed. This evaluation will inform possible medical management of TR. TTE assessment should also include an assessment of RV size and function using both 2-dimensional (2D) and 3-dimensional (3D) measurements. TAPSE, fractional area change, tissue Doppler systolic velocity, RV free wall strain, and 3D right ventricular ejection fraction (RVEF) are combined to evaluate RV function before and after TTVR.

TEE examination performed at various levels and multiplane angles allows for complete visualization and assessment of the TV apparatus and the RV. Four levels of imaging are recommended:[15,39] mid-esophageal, deep esophageal, transgastric, and deep transgastric (**Figure 4**). In patients who have had prior cardiac surgery, TEE visualization of the TV can be challenging given acoustic shadowing by left-sided prosthetic valve material or from the fibrous body of the heart, as well as a more horizontal lay of the heart. Due to the reduced distance between the TEE probe and the TV, deep esophageal, and transgastric views are associated with improved spatial and temporal resolution and eliminate left heart structures from the proximal imaging plane.

From any 2D view where the TV is well-imaged, a 3D volume can be acquired for multiplanar reformation during the procedure. **Figure 5** depicts 3D imaging of different TTVR devices. Although less relevant than for T-TEER, the ability to visualize the TV leaflets, subvalvular apparatus and surrounding landmarks remains important—particularly for TTVR devices with subannular leaflet anchoring. 3D imaging allows for real time characterization of TV leaflet morphology, subvalvular anatomy, and RV size and function, thus providing additional information for interventional procedural planning. In contrast to T-TEER, real-time multiplanar reconstruction is essential during implantation of TTVR devices to confirm device position, trajectory, and appropriate anchoring, while avoiding cardiac injury.

**INTRACARDIAC IMAGING.** Multiple 3D intracardiac echocardiography (ICE) imaging catheters are available and may be considered as adjunctive imaging

**FIGURE 2 Functional Improvement After EVOQUE Transcatheter Tricuspid Valve Replacement**




Functional changes after transcatheter tricuspid valve replacement. Improvement in NYHA functional class, Kansas City Cardiomyopathy Questionnaire (KCCQ) score, and 6-minute walking test distance after EVOQUE transcatheter tricuspid valve replacement as reported by TRISCEND and TRISCEND II. *Kodali et al.[56] **Hahn RT, et al.[26]

modalities when TEE resolution is limited. Although currently used to complement TEE imaging, in the future, 3D ICE may become a standalone modality for imaging during TTVR, if higher temporal/spatial resolution in a wider field of view can be achieved.[40-43]

**CARDIAC COMPUTED TOMOGRAPHY.** Electrocardiogram-gated cardiac computed tomography (CT) is an essential imaging modality for TTVR screening given its ability to image all aspects of device delivery (ie, femoral access, caval veins offset) and anchoring (leaflets and annulus), as well as relevant adjacent anatomic structures (ie, right coronary artery, subvalvular apparatus, position of papillary muscles, caval veins, CIED leads) with high temporal and spatial resolution.[44] Cardiac CT can also evaluate right-sided heart function and dimensions[45,46] and be used for virtual valve simulation, fusion imaging, and 3D printing. Dedicated protocols are required[47] typically using ECG-triggered or 1-beat acquisitions of multiphasic data sets covering the entire cardiac cycle in 5% to 10% time intervals with a thin-sliced reconstruction ≤1 mm and optimized contrast enhancement of the right cardiac chambers (plus jugular veins in case of jugular access). For femoral access devices, a delayed phase acquisition of the abdomen and pelvis for evaluation of the inferior caval, iliac, and femoral veins may improve the prediction of device approach angles and height. **Figure 6** displays the CT-based work-up of a patient considered for TTVR. Following device implantation, CT is useful for evaluating device positioning, leaflet morphology or complications (**Figure 7**).

**CARDIAC MAGNETIC RESONANCE.** Cardiac magnetic resonance (CMR) imaging represents an important adjunct for the accurate and reproducible assessment

of RV function, wall motion abnormality, RV volume, and chamber quantification.[48,49] CMR plays a unique role in identifying RV remodeling and fibrosis and is the gold standard for tissue characterization using native $T_1$ imaging and delayed gadolinium enhancement. However, data are lacking regarding the clinical relevance of detected RV fibrosis. Regurgitant volume and fraction for quantitative assessment of TR are calculated using right-sided chamber volume along with phase contrast pulmonic flow. In analogy to cardiac CT, imaging protocols should account for the dilation of the RV and RA and include 4-chamber, RV inflow-outflow, and RV short-axis images in its entirety.

### SUMMARY OF THE DIAGNOSTIC WORK-UP.

- Preprocedural imaging should be performed in an euvolemic, compensated state and the weight of the patient recorded at the time of screening for comparative purposes.
- Both 2D and 3D, TTE and TEE multilevel imaging of the TV are essential steps for patient screening.
- Deep esophageal and transgastric TEE improve the proximity of the probe to the TV and thereby might optimize spatial resolution for multiplanar reformation techniques.
- 3D ICE imaging may be considered when TEE imaging quality is limited.
- Cardiac CT allows for precise measurements of the TV apparatus, RV anatomy and function, as well as the venous access route and CIED lead position.
- CMR provides additive information regarding RV function and TR severity and allows for tissue characterization.

## RIGHT HEART CATHETERIZATION

Right heart catheterization (RHC) plays a crucial role to confirm the diagnosis of severe TR and assess hemodynamics and alterations of ventricular and pulmonary vascular function. In patients with severe TR, ubiquitous elevation of the invasive pressures caused by volume overload is typically observed. The RA pressures are elevated (>6 mm Hg) with a v-wave generally exceeding 15 mm Hg and a change of the typical RA waveform. In severe cases, the RA pressure profile becomes “ventricularized” and resembles the RV pressure profile with occasionally visible pulsation at the venous access site. Elevated RV end-diastolic pressure suggests relevant RV dysfunction.

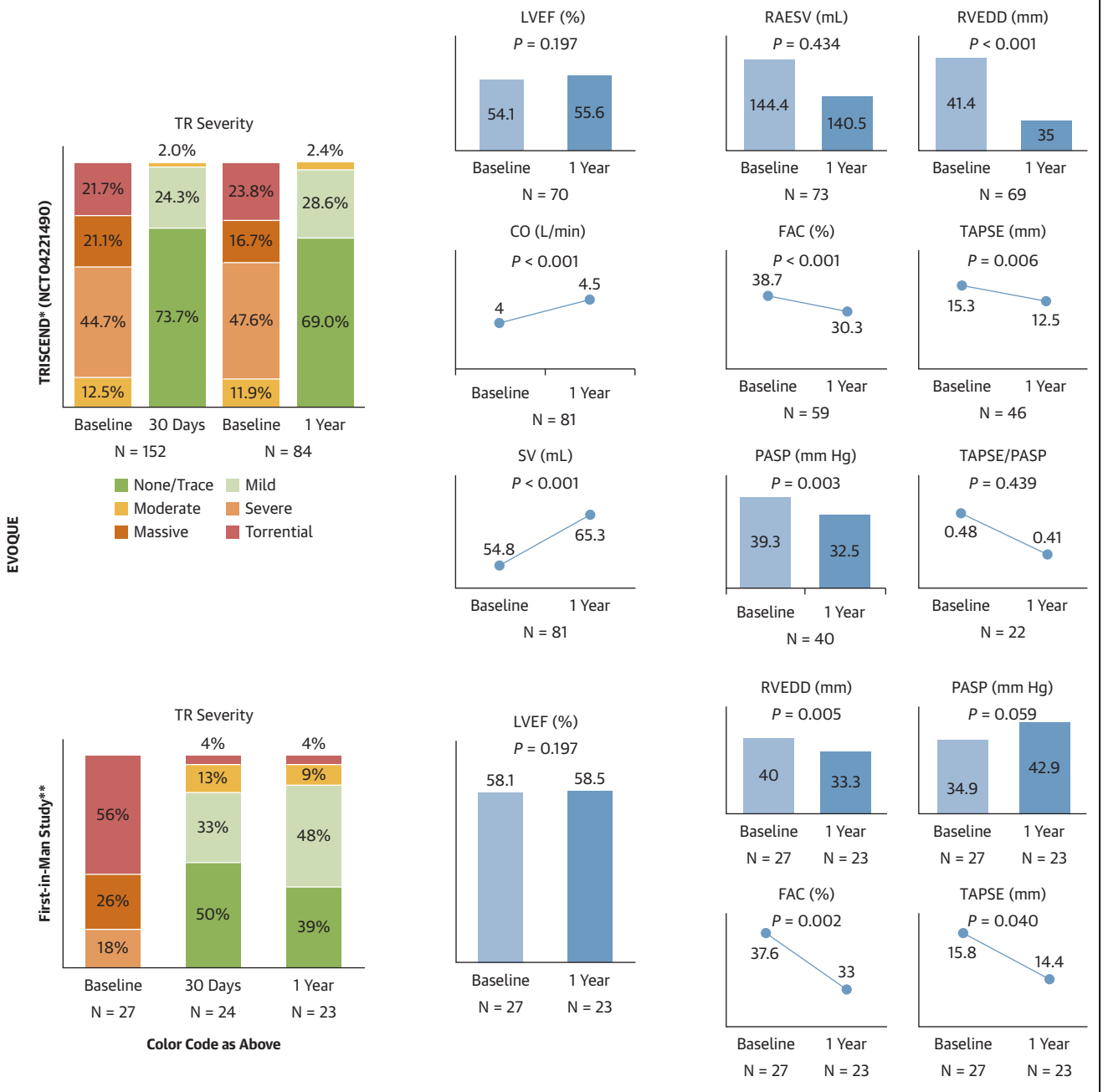
The calculation of pulmonary vascular resistance (PVR) plays an important role, because echocardiography can underestimate pulmonary pressures in the presence of severe TR primarily caused by inaccurate estimation of the RA pressure.[50,51] PH is not only thought to contribute to the development of severe secondary TR by inducing RV adverse remodeling and subsequent valve dysfunction, but is associated with adverse outcomes in patients undergoing TV surgery,[52] which is discouraged in this population.[53] Among patients with ventricular secondary TR, those with PH have the worst prognosis.[54,55] Indeed, TR reduction may lead to a sudden rise in afterload that, if not compensated by immediate increased contractility, may cause acute RV failure (afterload mismatch, see specific section below). Therefore, several TV intervention trials have excluded patients with a pulmonary artery pressure above 60 or 70 mm Hg or PVR above 4 WU.[56-58] While PH in general, especially precapillary PH, has been associated with adverse outcomes in patients undergoing interventional TR treatment, it remains unclear whether this is causative or reflects the inherent poor prognosis of PH patients.[55] High pressures on RHC have been associated with worse prognosis after T-TEER, particularly in patients with divergent, low pulmonary artery pressures estimated by TTE, likely representing the population with the highest RA pressures.[59] High RA pressures predict the occurrence of cardiogenic shock following surgical or transcatheter intervention.[60]

RHC-derived systolic pulmonary artery pressure (sPAP) can also be used to calculate the ratio of TAPSE to sPAP as a surrogate for RV to PA coupling that corresponds to the interplay of ventricular and arterial function—often referred to as ventriculo-arterial coupling. Invasive and noninvasive coupling indexes have prognostic utility in patients undergoing TR interventions, eg, a $TAPSE/sPAP_{echo}$ ratio of <0.41 was a predictor of worse outcomes.[61] Given the potential discrepancy between echocardiographic and RHC-derived pressure measurements, RHC may be preferred for accurate $TAPSE/sPAP_{invasive}$ assessment.[62,63] Patients with an uncoupled state may have the highest risk of acute RV failure following total TR abolishment using TTVR—although data to support this hypothesis are lacking so far.

### SUMMARY OF THE USE OF RIGHT HEART CATHETERIZATION.

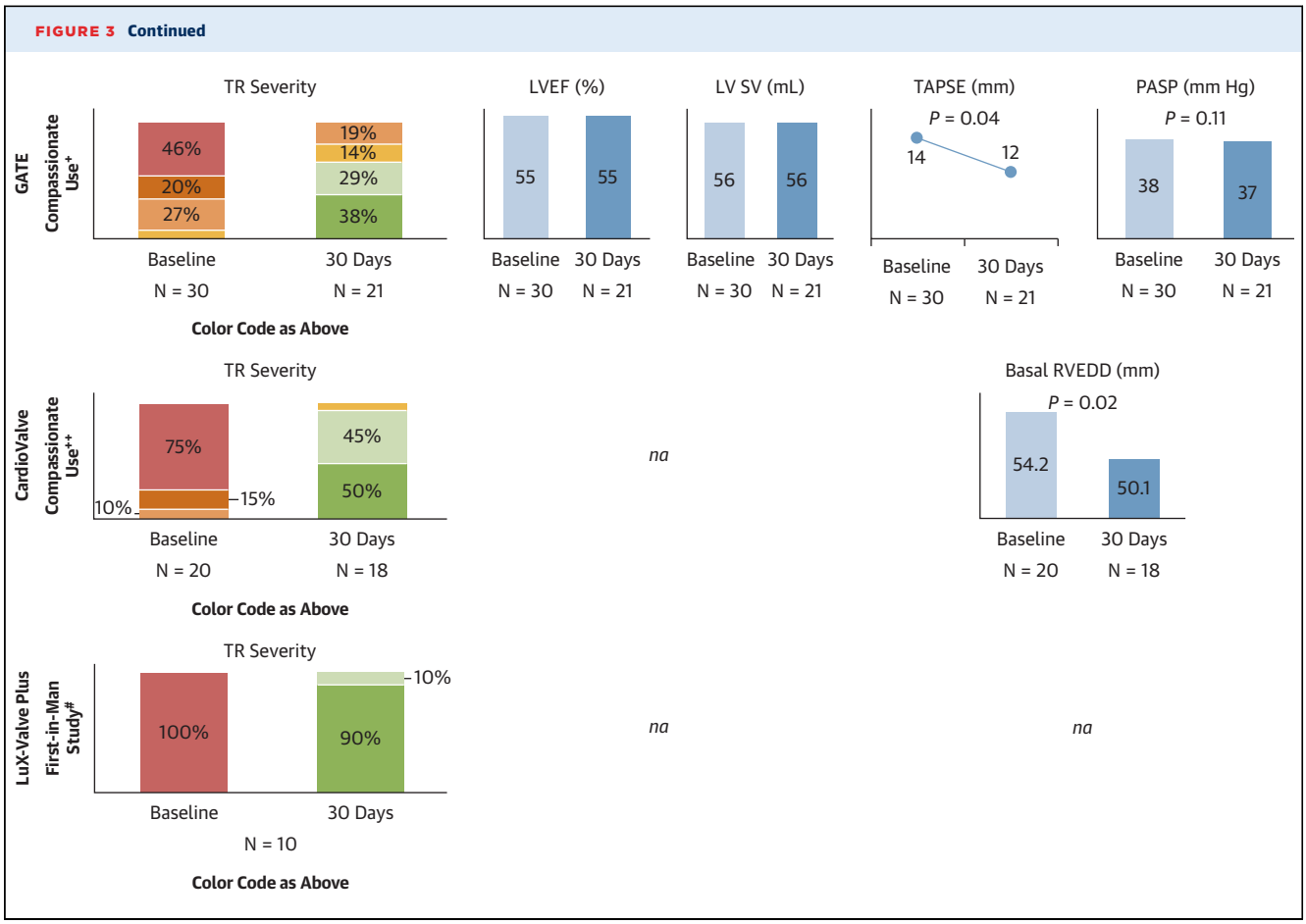
- RHC is recommended to assess hemodynamics and alterations of RV and pulmonary vascular function, as well as RA pressures.
- Invasive quantification of pulmonary pressures including the differentiation between precapillary and postcapillary PH, as well as the assessment of PVR should be routinely performed in TTVR candidates.

**FIGURE 3 Summary of Published Echocardiographic Results**




CO = cardiac output; FAC = fractional area change; LVEF = left ventricular ejection fraction; LV SV = left ventricular stroke volume; PASP = pulmonary arterial systolic pressure; RAESV = right atrial end-systolic volume; RVEDD = right ventricular end-diastolic dimension; TAPSE = tricuspid annular plane systolic excursion; TR = tricuspid regurgitation. *Kodali et al.[56] **Webb et al.[23] †Hahn et al.[22] ††Fam et al.[29] #Zhang Y et al.[27]

*Continued on the next page*



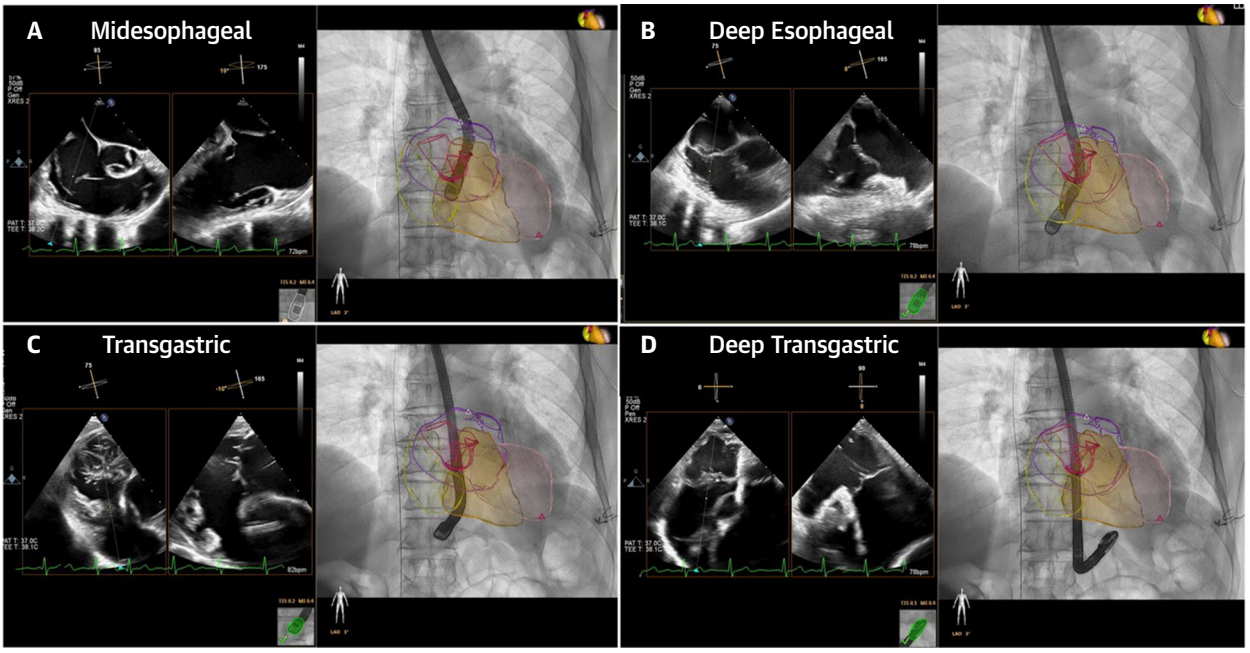

- Invasively measured ventriculo-arterial coupling indexes emerged as useful outcome predictors after TTVR, possibly superior to echocardiographically estimated coupling coefficients.
- Because patients with severe PH ($sPAP_{invasive}$ >60-70 mm Hg or PVR >4 WU) have been excluded from TTVR trials, the safety and efficacy of TTVR in this patient population remains unclear.

## INDICATIONS FOR TTVR AND PATIENT SELECTION

**INDICATIONS FOR TTVR.** As illustrated by the proposed treatment algorithm outlined in Figure 8, patients with severe symptomatic primary or secondary TR at prohibitive or high surgical risk according to an interdisciplinary Heart Team should be evaluated for TV interventions, whereas surgery is an option in selected low-risk patients with isolated or combined moderate or severe TR. Because quality of life improvement is the only benefit of TV interventions proven by randomized control trial at 1 year so far, patients reporting reduced quality of life, as well as those with previous HFHs should be prioritized for treatment. Patients with severe TR often present with multiple comorbidities, and the potential for improvement, as well as the anticipated life expectancy, have to be integrated into the interdisciplinary discussion to avoid futility. Recently, evidence of small, but statistically significant improvements of liver and renal function were detected after successful T-TEER and associated with better clinical outcomes.[64] Although preliminary, these data encourage the integration of biomarkers into the decision-making process. No clear cutoffs exist regarding RV dysfunction and PH, 2 essential parameters that need to be taken into consideration when deciding about treatment indication and modality.

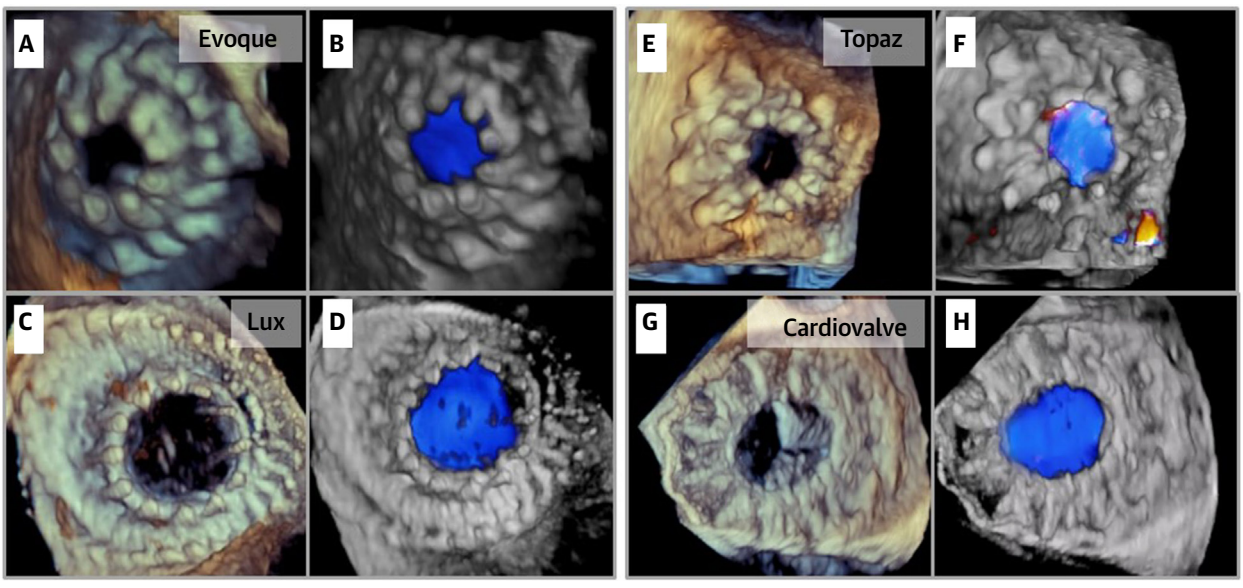
**CONSIDERATIONS FOR DEVICE SELECTION.** Device selection for TV interventions remains a complex topic with uncertainties concerning indications and appropriate clinical scenarios for each modality. In current clinical practice, T-TEER is an attractive choice based on favorable safety profile, broad

**FIGURE 4** TEE Imaging Levels of the Tricuspid Valve for Transcatheter Tricuspid Valve Replacement Guidance



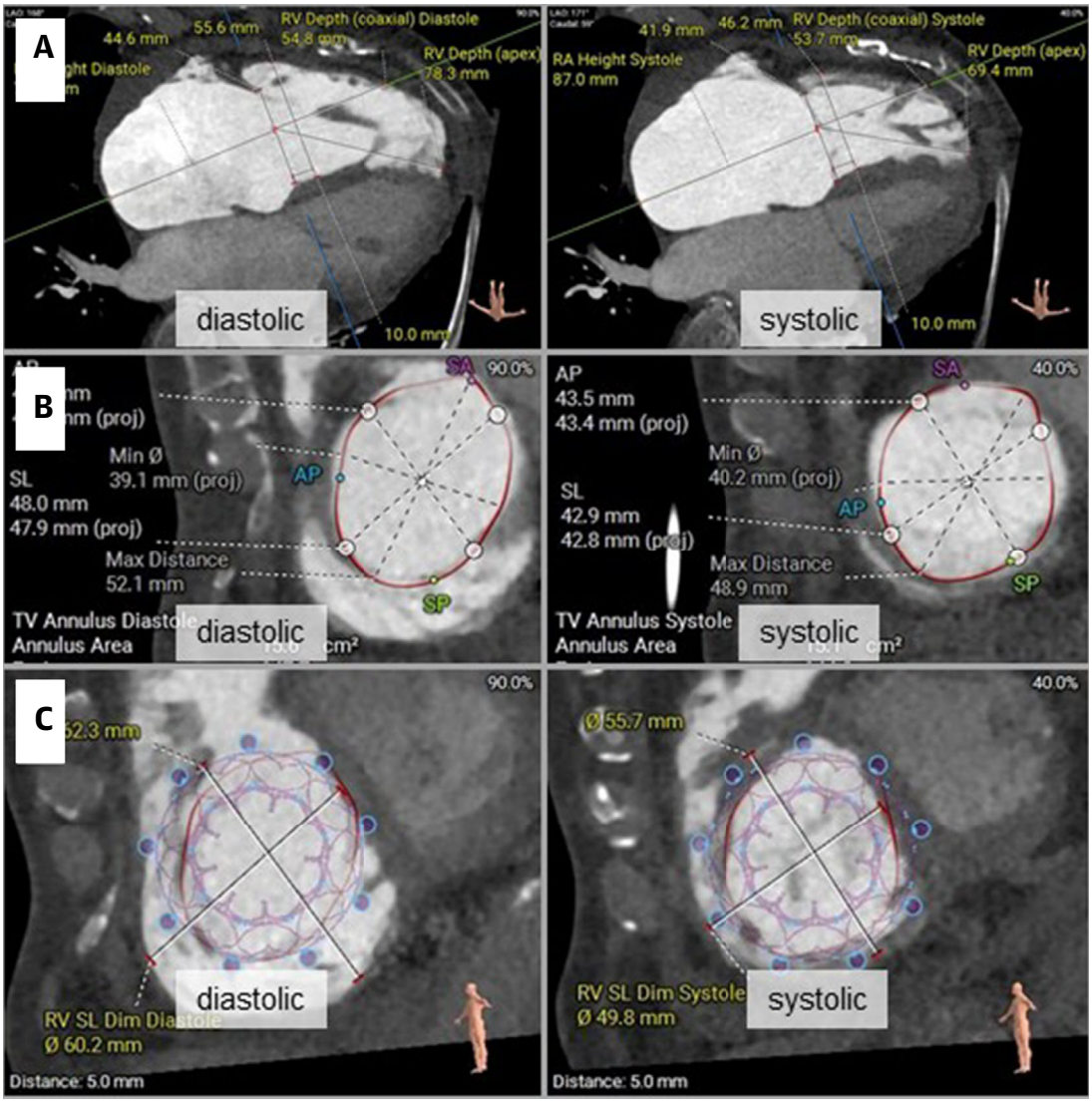

Four levels of tricuspid valve imaging: mid-esophageal, deep esophageal, transgastric, and deep transgastric, with the respective probe positioning in fluoroscopy.

**FIGURE 5** Visualization of Different Transcatheter Tricuspid Valve Replacement Devices Using 3-Dimensional Transesophageal Echocardiographic Imaging




3-dimensional transesophageal echocardiographic imaging allows for visualization of transcatheter tricuspid valve replacement devices including color Doppler (A and B: EVOQUE; C and D: LuX-Valve Plus; E and F: Topaz Valve; G and H: Cardiovalve).

**FIGURE 6** Computed Tomography-Based Work-Up Before Transcatheter Tricuspid Valve Replacement

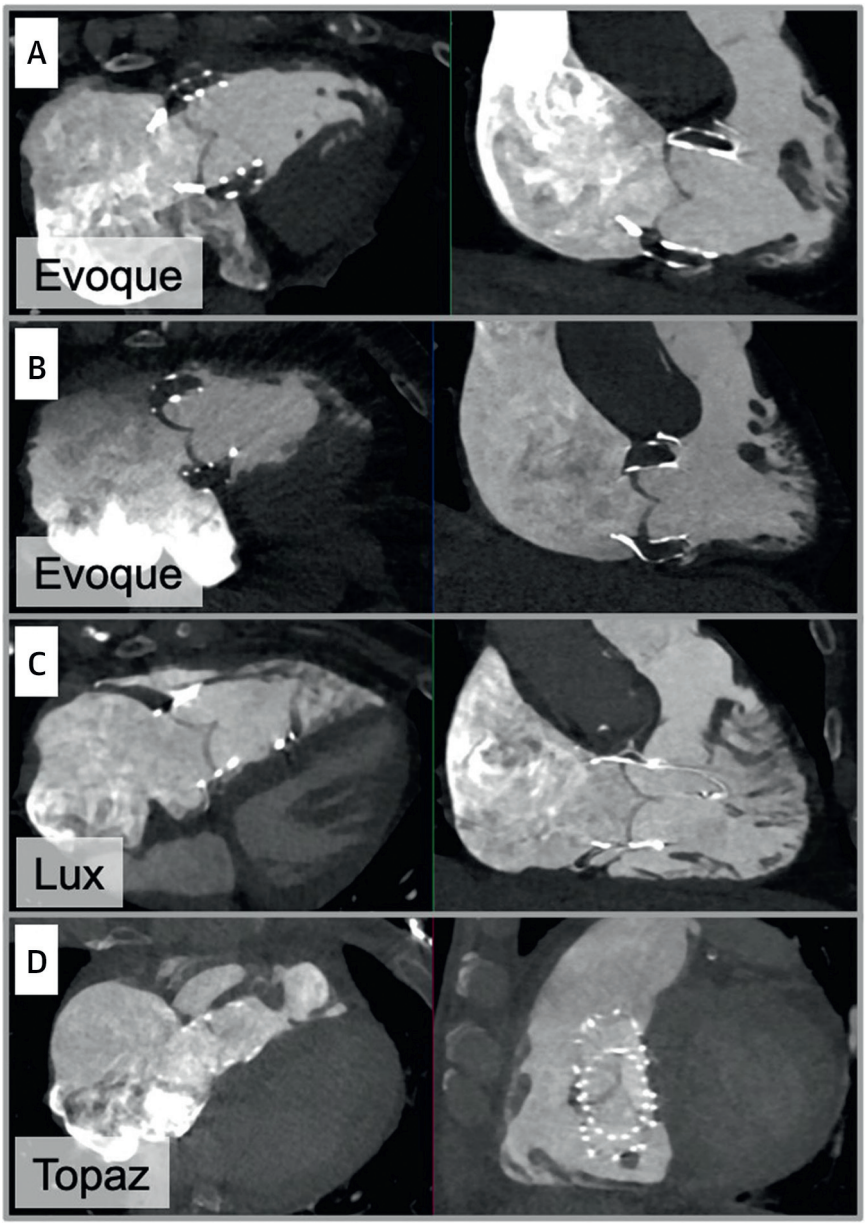



Computed tomography-based work-up of a patient being considered for transcatheter tricuspid valve replacement. AP = anteroposterior commissure; Dim = dimension; RA = right atrium; RV = right ventricular; SA = septo-anterior commissure; SL = septo-lateral diameter; SP = septo-posterior commissure; TV = tricuspid valve.

availability, and lower costs. However, T-TEER is less effective in reducing TR than TTVR and significant residual TR (eg, more than moderate, has been linked to worse prognosis).[13] Thus, it is currently unclear if T-TEER should be considered as the first-line therapy, whereas TTVR is reserved for patients with challenging or not suitable anatomy, or if a broader indication for TTVR will improve long-term outcomes. Accordingly, the relative use of TTVR compared with TV repair will depend on forthcoming evidence and future strategy trials, while preliminary results seem to confirm the importance of adequate TR reduction on prognosis and quality of life.[57,65]

Device selection should be based on several considerations including clinical and anatomical factors, as well as the anticipation of the need for subsequent procedures (lifetime management) (**Figure 8**).[66] Because tricuspid transcatheter valve durability is unknown and longer-term data following TV

**FIGURE 7** **CT Imaging Is an Additional Tool for Visualization of Valve Positioning and Leaflet Morphology After TTVR**

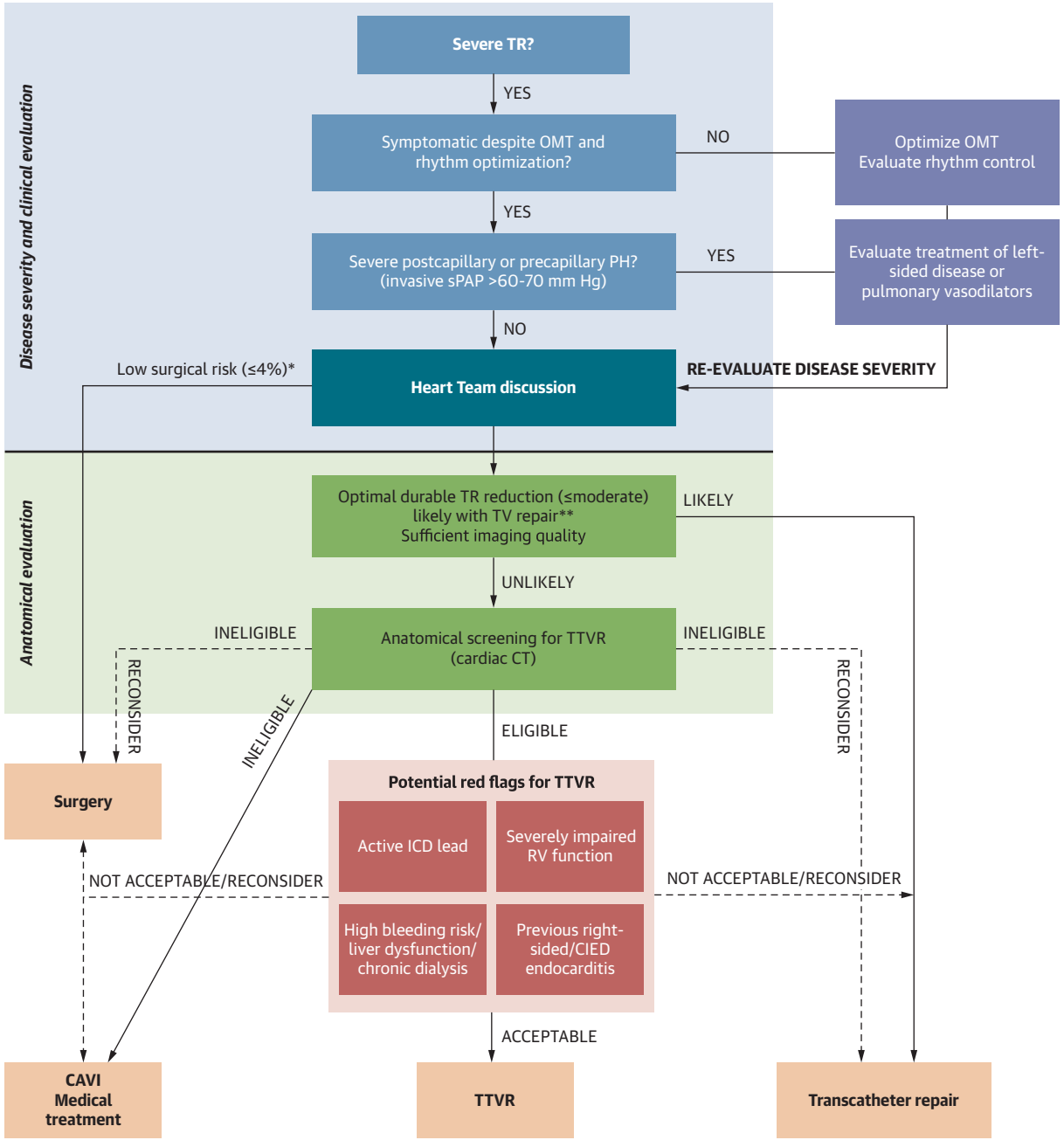



(A) Shows an EVOQUE TTVR device with pristine leaflets, while (B) provides an example for a patient developing HALT after TTVR using the EVOQUE device. (C and D) Represent CT imaging of patients who underwent TTVR using the LuX-Valve Plus (C) and Topaz Valve (D). HALT = hypoattenuated leaflet thickening; CT = computed tomography; TTVR = transcatheter tricuspid valve replacement.

interventions still limited, the latter point remains speculative. Decision-making should integrate all the considerations described in the following paragraphs.

**ANATOMY OF THE TRICUSPID VALVE AND SUBVALVULAR APPARATUS.** TV anatomy is variable and complex with 3 leaflets in about 60% of the patients, while 40% have either 2, 4, or even more leaflets.[67] The presence of multiple leaflets and indentations complicates the correct anatomical interpretation and adequate TR reduction. Increasing anatomical valve complexity (**Figure 9**) has been associated with impaired outcomes following T-TEER,[68] but not with other techniques, including direct annuloplasty[69] and TTVR. Recently, the GLIDE scoring system has been developed to predict intraprocedural reduction of TR based on 5 parameters:

**FIGURE 8** Treatment Algorithm for Patients With Severe TR Focusing on the Implementation of TTVR

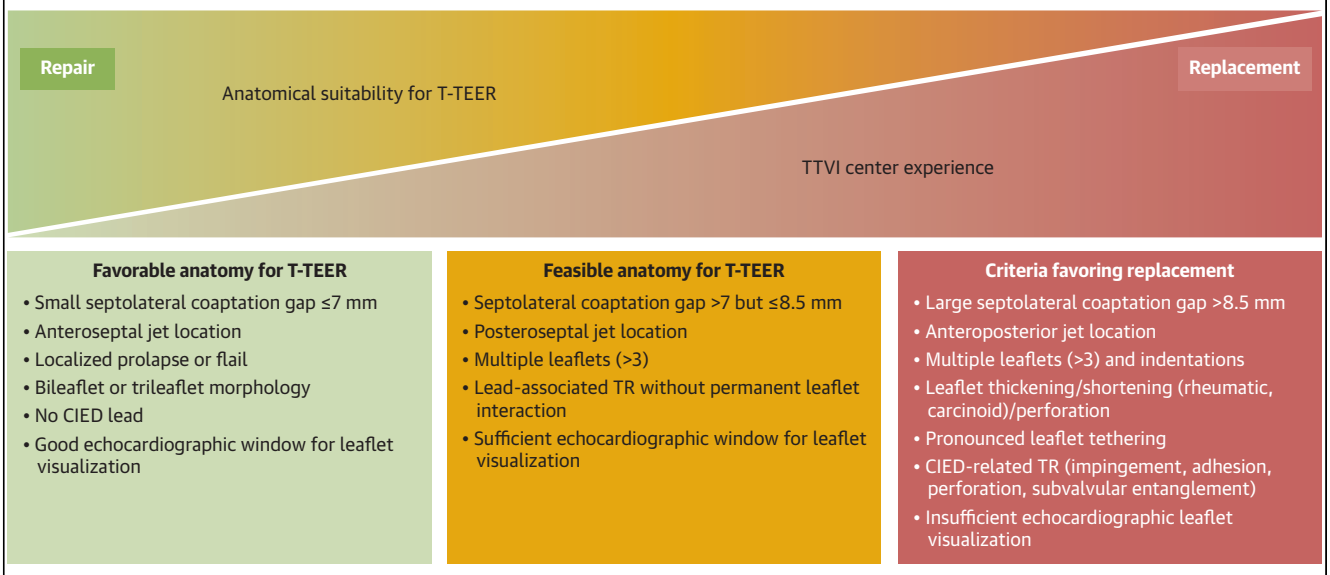



*According to dedicated scores for patients with TR (eg, TRI-SCORE, STS); **See also Figure 9. CAVI = caval valve implantation; CIED = cardiac implantable electronic device; ICD = implantable cardioverter-defibrillator; OMT = optimal medical treatment; PH = pulmonary hypertension; sPAP = systolic pulmonary artery pressure; other abbreviations as in Figures 3, 6, and 7.

*g*ap size, *l*ocation of jet, *i*mage quality, *d*ensity of chordal structures, and the *e*n-face TR morphology.[70] TR reduction ≥2 grades and residual TR ≤ moderate were observed in >90% of patients with GLIDE scores of 0 and 1 and in only 5.6% and 16.7% of those with GLIDE scores ≥4.

Subvalvular anatomy is particularly important for TTVR as transcatheter valve delivery may be impeded

**FIGURE 9 Anatomical Factors Involved in the Decision to Repair or Replace the Tricuspid Valve**




T-TEER = transcatheter tricuspid edge-to-edge repair; TTVI = transcatheter tricuspid valve intervention; other abbreviations as in Figures 3 and 8.

by high-seating subvalvular structures. The distance of the papillary muscles or moderator band from the TV annulus is important during TTVR screening and cutoffs depend on specific valve design and their projection into the RV.

**JET LOCATION AND COAPTATION GAP.** Non-anteroseptal jet location, pronounced leaflet restriction and tethering, as well as a large coaptation gap are predictors of suboptimal TR reduction after T-TEER.[71,72] Thus, patients with large central gaps, as well as those with nonanteroseptal (in particular, anteroposterior) jets might be preferably considered for TTVR if appropriate TR reduction using T-TEER seems unlikely (Figure 9).

**RIGHT HEART ANATOMY AND FUNCTION.** RV length and annulus dimensions are intimately linked to TR severity and progression, as well as the amount of leaflet tethering.[73] Leaflet tenting height and larger RV dimensions both have been associated with worse outcomes after T-TEER.[74,75] In contrast, small right atrial height and RV length can be prohibitive for valve implantation depending on catheter design, because height-gaining maneuvers (beyond simple "*wire push*") are not always possible. In this constellation, the use of the left transfemoral venous access might be considered as an alternative because it may naturally increase the approaching height.

Although no dedicated data have been published on this topic so far, the risk of afterload mismatch might be higher after TTVR compared with T-TEER because of abrupt and complete TR abolition, but also a selection bias towards patients with more challenging anatomy undergoing TTVR. Patients with severely reduced RV function, as well as those with a reduced ventriculo-arterial coupling may not be appropriate candidates for TTVR (or other tricuspid procedures) because this constellation is associated with higher postprocedural mortality.[61,76]

**LEAD INVOLVEMENT IN TR GENESIS.** Although TTVR might be a preferably considered method in patients with lead-related TR, in particular in cases of adhesions/interactions between leads and leaflets/papillary muscles, subvalvular entanglement, or perforation, it necessitates jailing of the previously implanted RV lead (unless transvenous lead extraction is performed as a preparatory step). The challenges of TTVR in CIED patients are discussed in a later dedicated section.

**REPEAT PROCEDURES AND LIFETIME MANAGEMENT.** Theoretically, TTVR allows for repeat procedures, ie, second implantation of a balloon-expandable valve; this need is difficult to anticipate because transcatheter valve durability in the tricuspid position is unknown. On the other hand, TTVR represents an

attractive bailout option for patients with detached (and maybe in the future still attached) T-TEER devices.[77]

**SPECIFIC INDICATIONS FOR TTVR.** Beside the previously mentioned anatomical considerations, some specific circumstances favor TTVR because of mechanistic and practical considerations. This includes restricted leaflet opening (eg, carcinoid syndrome or rheumatic TV disease),[78] long-standing lead-related TR (potentially with multiple leads crossing the annulus), single-leaflet device attachment of a single implant[77] with persistent relevant TR, endomyocardial biopsy-related leaflet or chordal damage, as well as selected patients in whom imaging quality is insufficient for T-TEER. Indeed, imaging requirements for some TTVR devices (among others: LuxValve Plus, TOPAZ) are lower in terms of resolution and leaflet assessment than for T-TEER with steeper learning curve for interventional imaging specialists.

**SUMMARY OF CONSIDERATIONS FOR TTVR OVER TRANSCATHETER REPAIR TECHNIQUES.**

- Anatomical factors of TV complexity favoring TTVR
  - Multiple leaflets (eg, ≥4 leaflets);
  - Large coaptation gap (eg, ≥8.5 mm);
  - Non anteroseptal TR jet location;
  - Pronounced leaflet tethering;
  - CIED patients with lead-related TR (see also the following text);
  - Leaflet retraction, eg, carcinoid syndrome.
- TTVR is an option in case of single leaflet device attachment after single-implant with persistent relevant TR.
- Patients with severely reduced RV function as well as reduced RV-PA coupling might not be ideal candidates for TTVR or even any tricuspid therapy.
- Insufficient echocardiographic imaging quality for T-TEER.

## PATIENT PREPARATION

Patients referred for TR evaluation are typically elderly with comorbidities. A thorough clinical assessment and optimization of associated conditions (eg, obstructive lung disease, anemia, kidney disease, neurological disorders) with a particular focus on accompanying cardiac disorders (eg, left-sided systolic or diastolic heart failure, other valve disorders, and atrial fibrillation) will not only help to better predict the potential benefit of treating TR, but also minimize the risk of procedural complications. Guideline-directed medical heart failure therapy should be optimized according to disease etiology (HFrEF or HFpEF) and resynchronization, as well as AF rhythm or rate control considered, if appropriate. In patients with precapillary PH, pulmonary vasodilators may be initiated, when appropriate, before TTVR, to improve RV function and reduce TR severity.[79] A comprehensive assessment of left- and right-sided atrial and ventricular function including hemodynamics are crucial before TTVR. The LV response to an increased preload after successful TR reduction is largely unknown and requires further investigations. Indeed, improved cardiac output after successful TR treatment may lead to worsening of a preexisting mitral regurgitation because of acute elevation of LV end-diastolic pressures. In the setting of HFpEF, the same phenomenon might lead to pulmonary congestion.

Because patients are typically referred at an advanced stage, systemic fluid retention is a common finding. Volume overload affects TR severity, as well as tricuspid annular and right heart chamber dimensions. In addition, it has been proposed that volume overload may impair LV filling because of ventricular interdependence[80] or may cause a paradoxical hyper-circulatory state resulting from hepatic and renal congestion eventually leading to neurohumoral counter-regulation.[81] These hemodynamic changes, eventually accompanied by pleural effusion or ascites, may impact periprocedural and potentially also longer-term outcomes. Systematic assessment and identification of symptoms and signs of volume overload should therefore be the first step when evaluating patients for transcatheter tricuspid therapy.

If systemic fluid retention is present, diuretic regimens should be adapted either as oral outpatient therapy under constant weight control or intensified intravenous treatment with in-hospital monitoring ("prehab") until reaching euvolemic conditions.[82] Continuous monitoring of the diuretic response by measurement of urine output and, if necessary, urine sodium concentration with adaptation of the diuretic dose (eg, doubling) are recommended.[83]

**SUMMARY OF PATIENT PREPARATION.**

- Guideline-directed medical heart failure therapy, including resynchronization and AF rhythm and/or rate control should be implemented before procedural screening.
- Treatable left-sided conditions (eg, severe aortic or mitral valve disease) should be addressed first.

- Initiation of pulmonary vasodilators should be considered in patients with precapillary PH (World Health Organization group 1).
- Preprocedural decongestion to achieve euvolemic conditions is essential and might improve procedural outcomes.

## SPECIFIC CHALLENGES OF TTVR

**CIED LEAD(S).** Studies performed in TTVR patients found specific challenges potentially affecting procedural safety that need careful anticipation, management, and follow-up (**Central Illustration**). About one-third of the patients referred for TTVI have CIED lead(s),[56] which may be bystanders (lead-associated TR), or directly involved in the mechanism of TR because of leaflet/subvalvular adherence or interference, impingement, or perforation (lead-related TR). Importantly, lead-related TR is a common reason for T-TEER screen failure and subsequent consideration of TTVR. Lead jailing or entrapment, however, may eliminate the possibility of lead extraction should there be a pacemaker infection.[84] The failure to extract a lead in the setting of infection is associated with poor survival. Risk scores to predict pacemaker infection may help inform shared decision-making. Given that lead extraction has inherent albeit low risks and might compromise TTVR eligibility because of leaflet damage, a multidisciplinary individualized evaluation of the risks and benefits of TTVR with CIED lead jailing against transvenous lead extraction is necessary. Dwelling time and previous CIED infections should be taken into account. In some cases, particularly with multiple RV leads, lead extraction may be required to allow safe device anchoring. Device interrogation should be systematically and regularly performed before and after TTVR to establish device dependency and document lead impedance(s). In patients with implantable cardioverter-defibrillator, the frequency and type of antitachycardic therapy is a crucial parameter because jailing of an active defibrillator lead is not recommended at this stage. Case reports and future registries may provide further insights into the safety of jailed pacemaker and ICD leads.

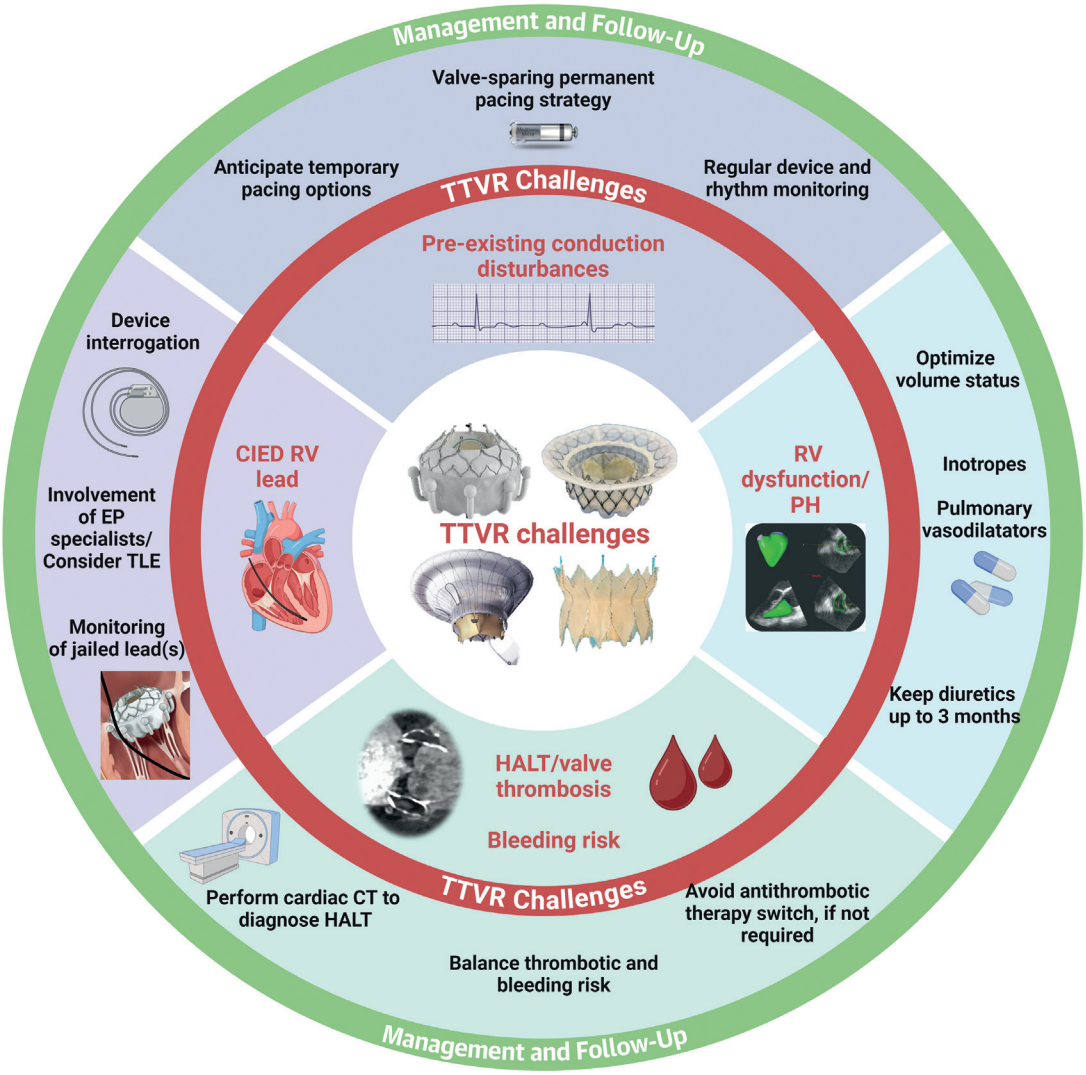
Although jailing CIED leads did not negatively affect short-term outcomes, the long-term risks of lead dislodgement, malfunction or endocarditis remain unknown. Functioning jailed leads require particular attention and frequent follow-up (ideally using remote monitoring).

**NEW-ONSET CONDUCTION DISTURBANCES DURING/AFTER TTVR.** Published rates of new-onset conduction disturbances (NOCD) from clinical studies range between 2% to 25%[29,56] and vary according to TTVR devices. The majority of NOCDs are observed within 72 hours after the procedure. However, unpublished data from the TRIPLACE (Global Multicenter Registry on Transcatheter TRIcuspid Valve RePLACEment) registry report that conduction disturbances can occasionally occur even beyond this timeframe. Device characteristics that may potentially contribute to NOCD risk include the degree of oversizing, radial force, and subannular anchors. Patient factors that predispose to NOCD are less clear but may include baseline left bundle branch block or slow atrial fibrillation. Because predisposing factors have not been elucidated yet, postprocedural rhythm monitoring is recommended throughout hospital stay. The ideal monitoring duration is currently unclear and may vary according to the degree of oversizing and the type of TTVR device. Home monitoring may be considered for high-risk patients with preexisting conduction disturbances or within the framework of studies. The increasing commercial experience will contribute to define the duration of in-hospital and home monitoring optimizing patient's safety and length of stay.

Importantly, operators should be prepared for intraprocedural NOCD and acute lead dislodgment or dysfunction. Temporary pacing strategies include transcutaneous delivery wire, coronary sinus, or LV pacing, as well as placement of a pacing wire through the new TTVR device. For permanent pacing, the preferred valve-sparing options include the placement of a coronary sinus lead or the implantation of a leadless pacemaker. Of note, lead placement into the coronary sinus in TR patients with remodeled anatomy may be challenging, and delayed lead dislodgement is a potential concern. Leadless pacemakers are attractive but require to recross the valve with a large-bore delivery sheath. Although not the first-line option, echocardiography-guided RV lead placement can be an alternative, in particular when aiming for left bundle branch pacing. Further studies and device iteration are needed to minimize and better predict NOCD after TTVR.

**BLEEDING VS THROMBOTIC COMPLICATIONS.** Periprocedural bleeding complications are frequent after TTVR and an important cause of morbidity and mortality. In the TRISCEND I study, severe bleeding occurred in 27% of patients at 30-day follow-up, mainly caused by vascular complications and gastrointestinal bleeding.[24]

**CENTRAL ILLUSTRATION** **Specific Challenges of Transcatheter Tricuspid Valve Implantation and Their Management**



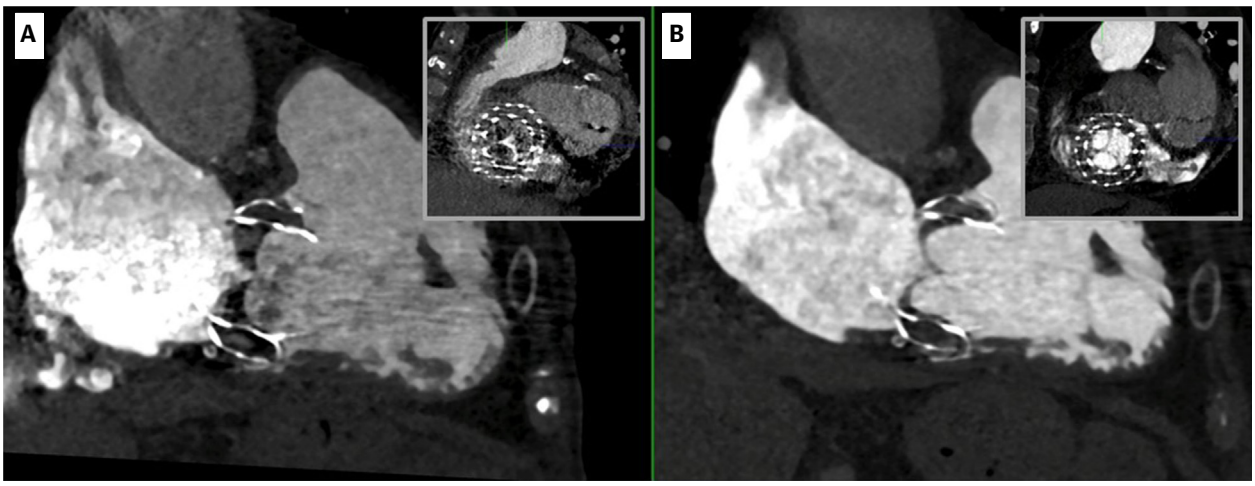

**Hausleiter J, et al. JACC. 2025;85(3):265–291.**

CIED = cardiac implantable electronic device; CT = computed tomography; EP = electrophysiologist; HALT = hypoattenuated leaflet thickening; PH = pulmonary hypertension; RV = right ventricle; TLE = transvenous lead explanation; TTE = transthoracic echocardiography; TTVR = transcatheter tricuspid valve replacement.

With increasing experience, the rate of severe bleeding complications decreased to 10.4% in TRISCEND II. Although prospective studies are needed to determine optimal TTVR bleeding avoidance strategies, general principles include among others: 1) short-term discontinuation of oral anticoagulation (OAC) before the procedure (see section "Antithrombotic Treatment Strategy"); 2) ultrasound-guided venous access below the inguinal band; 3) ideally avoidance of surgical cut-down or femoral artery puncture; and 4) confirmation of hemostasis before initiation of anticoagulation.

The risk of bleeding complications under anticoagulation therapy needs to be balanced with the risk of thrombotic valve complications including hypoattenuated leaflet thickening (HALT)

**FIGURE 10 Computed Tomography Imaging of a Patient With Valve Thrombosis After Transcatheter Tricuspid Valve Replacement**




After transcatheter tricuspid valve replacement in May 2021, the patient presented with valve thrombosis at 2-month follow-up computed tomography (A). Switching the oral anticoagulation therapy from a direct oral anticoagulant to vitamin K antagonist (target international normalized ratio 2.5-3.5) led to improvement after 9 months (B). Short-axis reconstructions of transcatheter tricuspid valve replacement with thickened leaflets are overlaid.

formation.[85] Figure 10 provides an example of a patient who developed valve thrombosis after TTVR, which improved after switching the oral anticoagulation regimen from a direct oral anticoagulant (DOAC) to vitamin K antagonist (VKA). Recommendations on the peri-interventional and postinterventional management of anticoagulation are summarized in the following dedicated section.

**ACUTE RIGHT HEART FAILURE/AFTERLOAD MISMATCH.** Sudden TR reduction in RV preload with increase in afterload may lead to acute afterload mismatch, with low cardiac output and RV failure requiring inotropic support to maintain perfusion. The incidence of RV failure is not consistently reported in TTVR studies but ranges between 0% and 2% (and up to 10% in early compassionate use reports).[29,86] Although usually transient, this complication may be fatal in some patients, particularly those with baseline NYHA functional class IV symptoms, severe RV dysfunction and severe precapillary PH; such patients were excluded from TTVR clinical trials.

Acute right heart failure needs to be detected early and is usually characterized by acute RV dilatation and dysfunction, as well as a drop of the invasively measured or estimated systolic pulmonary artery pressure, eventually followed by systemic arterial hypotension and cardiogenic shock. Inotropic support (eg, dobutamine, levosimendan, epinephrine, or milrinone) should be rapidly installed, possibly combined with vasopressors, even if no data exist regarding their efficacy in this context.[87] Afterload reduction with either inhaled or systemic pulmonary vasodilators may represent an essential therapy asset.

**SHARED DECISION-MAKING.** In contrast to T-TEER, which has been proven a low-risk procedure, TTVR has specific inherent challenges as described above, which need to be communicated with the patient during a shared decision-making process (prolonged monitoring for conduction abnormalities, potential bleeding complication, need for lifelong oral anticoagulation therapy, etc). On the other hand, symptomatic and outcome improvement have been clearly linked to successful TR reduction.[13,14,88] It remains speculative whether the higher TR reduction achieved by TTVR compared with T-TEER will translate into superior quality of life improvement and longer-term outcomes justifying the higher procedural risk. The role of the local Heart Team is therefore to integrate individual clinical and anatomical factors considering site experience and device availabilities to determine the treatment modality most likely to achieve durable TR reduction with acceptable risks.

**SUMMARY OF THE SPECIFIC TTVR CHALLENGES.**

- Intraprocedural temporary pacing, as well as postprocedural valve-sparing treatment strategies

of NOCD should be anticipated and discussed before TTVR.

- Although short-term outcomes of CIED lead jailing appear favorable, the long-term risks are unknown, and caution is therefore needed in patients with active ICD leads and pacemaker dependency, as well as those with previous CIED infection.
- Up to 25% of patients develop NOCDs after TTVR, predominantly within 72 hours after the procedure. Predisposing factors may include previous left bundle branch block and/or slow atrial fibrillation. In high-risk patients, ambulatory telemetry monitoring should be considered at discharge.
- Acute RV failure is a rare and often transient complication after TTVR requiring temporary inotropic support.
- A shared decision-making process needs to balance the potential risks and benefits of TTVR considering the preference of the informed patient.

## IN-HOSPITAL CARE

Besides the previously mentioned challenges, few additional aspects require particular attention during the hospital stay and the immediate postprocedural period. For proper management of TTVR patients, continuous communication and close collaboration between the subspecialties delivering care are crucial.

1. The postprocedural oral diuretic therapy should be continued to maintain an euvolemic status with constant body weight (under continuous daily weight monitoring). If tolerated by the patient, preprocedural dosages are often continued up to 3 months after valve implantation depending on the degree of oversizing and patient response. This may avoid early fluid overload and promote reverse RV remodeling. Reductions in diuretic therapy, especially in the early phase, should only be performed with great caution, if clinically necessary. Rapid fluctuations of the volume status may result in partial valve detachment and/or new paravalvular leakage because of the abrupt changes of the RV dimensions. This risk is believed to persist as long as valve endothelialization has not been completed. However, this does not apply to the rare case of polyuria following acute resolution of renal venous congestion. Because the interpretation of biomarker levels is challenging after TTVR (frequent increase of N-terminal pro-B-type natriuretic peptide), monitoring of urine output, clinical patient volume status, and weight are essential to prevent both acute right heart decompensation associated with worsened RV function, as well as dehydration in case of unnoticed polyuria.
2. TTE should be routinely performed before discharge to identify complications, and assess RV and valve function. Leaflet visualization should be routinely attempted to identify leaflet thrombotic complications that can occur early. At this stage, only relevant valve dysfunction would trigger a change of the antithrombotic therapy (in contrast to HALT without impact on hemodynamics; see the following dedicated section).
3. Systematic interrogation of jailed CIED lead is mandatory before discharge to document pacemaker-dependency and the electrical parameters of the system including for each lead the impedance, sensing, and pacing thresholds. If available, remote monitoring and alerts should be activated (in analogy to lead under alert/recall).
4. In case of valve dislocation, rapid surgical correction must be considered because clinical state can deteriorate rapidly. Relevant paravalvular leakage may be treated using a transcatheter approach, and hemolysis should be excluded.
5. Acute bioprosthesis dysfunction caused by misplacement, dislocation, or thrombotic complication has been infrequently reported. Anecdotal valve-in-valve implantation of a balloon-expandable transcatheter aortic valve has been performed with success in the EVOQUE valve.

### SUMMARY OF IN-HOSPITAL CARE.

- TTE should be routinely performed before discharge to identify complications and assess RV and valve function.
- Systematic interrogation of jailed CIED leads is mandatory before discharge.
- Postprocedural rhythm monitoring is recommended for all patients during hospital stay. Monitoring duration may vary according to the predisposing risks and the type of TTVR device
- Early discharge after the procedure (up to 72 hours after) is generally not recommended

## ANTITHROMBOTIC TREATMENT STRATEGY

The vast majority of patients considered for TTVR have a formal indication for OAC therapy caused by coexisting AF (92% in TRISCEND I). TTVR patients are usually at high risk for spontaneous and periprocedural bleeding caused by advanced age, hepatic and/or renal dysfunction, other comorbidities, concomitant anticoagulation therapy, large bore

vascular access, and periprocedural imaging with frequent intraesophageal TEE probe manipulations.[89] The following considerations for potential anticoagulation management strategies among patients undergoing TTVR are derived from previous TTVR studies, as well as from recommendations for CIED or small surgical or cardiac catheter ablation therapies.

In preparation for TTVR and in the absence of an absolute indication for oral anticoagulation (mechanical valves), short-term discontinuation of OAC before the procedure should be considered. Among patients on DOACs and based on baseline renal function, rivaroxaban, apixaban, or edoxaban are stopped for 24 to 48 hours preprocedure, whereas dabigatran may be stopped for 48 hours. In patients on VKA, a periprocedural international normalized ratio (INR) around 1.8 to 2.5 may be targeted without drug discontinuation. Bridging strategies with IV-heparin should be avoided—unless clinically mandatory, eg, in patients with mechanical heart valves—because they have been associated with increased risks for bleeding complications.

After achieving venous access using ultrasound guided puncture and insertion of the large-bore valve delivery system, ACT-guided anticoagulation >250 seconds with IV heparin should be maintained during the procedure. Heparin reversal with IV protamine has been performed at the end of TTVR procedures, although it is unclear whether this practice reduces the risk for periprocedural bleeding complications. The safety and optimal dosing of heparin reversal needs to be evaluated with increasing TTVR experience.

Due to the hemodynamic low flow/low pressure characteristics of the TV with predisposition to thrombus formation and early valve degeneration, OAC should be resumed after successful TTVR and in the absence of periprocedural bleeding. Although VKA patients may be continued with the usual INR maintenance dose administered at the day of the procedure, patients on DOAC may receive their next dose on day 1 after TTVR.

The optimal anticoagulation strategy—DOAC vs VKA—after TTVR is currently unknown, and a summary of recommendations depending on coexisting medical conditions is provided in the Supplemental Table 1. Patients with mechanical valves and those with concomitant rheumatic heart valve lesion should receive VKA. In all other patients and in the absence of evidence-based recommendations for the anticoagulation regimen after TTVR, it may be reasonable to maintain patients on the identical OAC regimen as before TTVR (*"no change strategy"*), because switches in drug regimen have been associated with increased bleeding risk. In general, patients on DOAC compared with VKA have more reliable anticoagulation and lower risk of major bleeding including intracranial hemorrhage with the exception of gastrointestinal bleeding. In patients with normal sinus rhythm and without other indication for oral anticoagulation, a minimum of a 3- to 6-month OAC regimen should be considered after TTVR, while subsequent OAC continuation vs an antiplatelet therapy needs to balance the individual long-term bleeding and thromboembolic/valve thrombosis risks. If OAC is stopped, close follow-up with repeated echocardiographic images is critical caused by the increased risk of leaflet thickening and thrombosis.

The concomitant administration of antiplatelet therapy in addition to OAC is usually not recommended because of increased risk of bleeding. In case of recent (within 6 months) myocardial infarction or percutaneous coronary intervention, dual antithrombotic therapy consisting of OAC and single antiplatelet therapy for a duration of 1 to 6 months may be considered.

### SUMMARY OF ANTITHROMBOTIC TREATMENT STRATEGY.

- In patients on OAC, short-term interruption should be considered, eg, cessation of DOAC 24 to 48 hours before TTVR; for VKA: aiming for INR target levels 1.8 to 2.5.
- Avoidance of "bridging" with IV heparin before the procedure—unless absolutely indicated (eg, for selected patients with mechanical heart valves).
- Target ACT levels of >250 seconds during the TTVR procedure.
- Heparin reversal with protamine may be considered at the end of the TTVR procedure.
- OAC continuation after confirmation of hemostasis, for example:
  - DOAC continuation on next day
  - VKA: continuation with target INR 2.0 to 3.0 after TTVR
- It may be reasonable to maintain the preprocedural anticoagulation strategy also after TTVR ("no change strategy"); in case of relevant valve dysfunction under DOAC, a switch to VKA may be considered.
- Concomitant antiplatelet therapy should be avoided, unless otherwise indicated.

## CLINICAL FOLLOW-UP

After TTVR, a standardized clinical follow-up is recommended. Many clinical sites currently perform outpatient follow-up at 30 days, 6 and 12 months, and

yearly afterwards. The follow-up visits usually include medical history and physical examination, laboratory evaluation, 6-minute walking distance, and a transthoracic echocardiogram (Table 3). Continuous effort should made to optimize medical therapy because the improved hemodynamic conditions may facilitate GDMT up-titration. The diuretic therapy should be continued to maintain constant body weight (under continuous daily weight monitoring). Changes in medication should be documented and CIED function confirmed, especially if the RV lead has been jailed. In addition, a tricuspid full-cycle CT may be considered during follow-up, eg, at 30 days, to document valve position and leaflet mobility, because CT is more sensitive to detect leaflet thickening than TTE. This might be of particular relevance in patients with insufficient TTE imaging quality or pathological echocardiographic findings. Although the clinical impact of increased leaflet thickening in the absence of valve dysfunction is currently unclear, change or intensification of the anticoagulant strategy may be considered depending on the severity of the findings to prevent a potentially associated earlier valve degeneration.

The endocarditis risk associated with TTVR is unknown, and patients should receive life-long endocarditis prophylaxis. Due to the usually high surgical risk of this population of patients, conservative antibiotic treatment should be attempted first, unless mechanical complications or abscess are already present.

### SUMMARY OF FOLLOW-UP CARE.

- Oral diuretic therapy should be continued to maintain an euvolemic status with constant body weight (under continuous daily weight monitoring).
- Patients with jailed CIED leads should undergo regular device interrogations.
- Patients should receive life-long endocarditis prophylaxis with adherence to best practices to avoid bloodborne infection.

## FUTURE DIRECTIONS AND CLINICAL TRIALS

Although a clear and reproducible benefit has been established on quality of life, heart failure symptoms, and RV reverse remodeling, unknows persist regarding a potential impact of TV treatment in general, and TTVR in particular, on hard clinical endpoints like HFH and mortality over the long-term. Future trials (Table 4) with planned 2-year follow-up, as well as the protocol-mandated 2-year follow-up of the Tri.Fr trial may contribute to elucidate these still open questions. Notwithstanding, future research should implement endpoints and measures of therapeutic success better adapted to patients with right heart failure, who, unlike left-sided disease, do not necessarily require hospitalization for the management of acute decompensation. On the same line, cost-effectiveness studies considering the particularities of TR patients should be conducted in analogy to transcatheter aortic valve replacement.

In addition, the role of TTVR in specific clinical scenarios like multiple valve disease, patients with atrial secondary TR, and those with cardiac implantable electronic device lead(s) will need separate investigations, as they represent distinct disease phenotypes. The most appropriate timing of an intervention, as well as the optimal antithrombotic treatment balancing the bleeding and thrombotic risk remain unknown. Future studies are also expected to perform device comparisons, especially between transcatheter repair and replacement.

Finally, imaging still represents one of the main challenges of tricuspid interventions, even if less demanding for TTVR. Further development of intracardiac echocardiography may open the path towards procedures performed in local anesthesia to minimize invasiveness in this multimorbid population of patients.

**TABLE 3 Components of Follow-Up Studies After Transcatheter Tricuspid Valve Replacement**

| |
|---|
| Medical history and physical examination, including edema score and NYHA functional class |
| Documentation of medication changes |
| Electrocardiogram |
| Laboratory values: hemoglobin, BNP, creatinine, eGFR, bilirubin, LDH, alkaline phosphatase, GGT, INR (if VKA anticoagulation), WBC, RBC, hematocrit, platelet count |
| 6-min walking distance |
| Quality of life assessment, eg, KCCQ or MLHFQ |
| Transthoracic echocardiography |
| CIED interrogation (if present) |
| Cardiac CT, eg, after 30 days, particularly in patients with insufficient TTE imaging quality or pathological echocardiographic findings |

BNP = brain natriuretic peptide; CIED = cardiac implantable electronic device; CT = computed tomogram; eGFR = estimated glomerular filtration rate; GGT = gamma-glutamyl transferase; INR = international normalized ratio; KCCQ = Kansas City Cardiomyopathy Questionnaire; MLHFQ = Minnesota Living With Heart Failure Questionnaire; RBC = red blood cell; TTE = transthoracic echocardiogram; VKA = vitamin K antagonist; WBC = white blood count.

## CONCLUSIONS

TTVR is currently performed at specialized centers, mainly in T-TEER-ineligible patients. Following the recent CE and FDA approval of the EVOQUE system in

**TABLE 4 Upcoming Large-Scale Studies Investigating Tricuspid Transcatheter Valve Interventions**

| | 2025 | | 2026 | | | 2027 |
|---|---|---|---|---|---|---|
| | TRI.Fr | CLASP II TR | TRIC-I-HF | TRINITY | TRICAV | TRACE-NL |
| Registration number | NCT04646811 | NCT04097145 | NCT04634266 | NCT05436028 | NCT06137807 | NL81645.100.22 |
| Sponsor | French Ministry for Health (PHRC-N) | Edwards Lifesciences | Deutsches Zentrum für Herz-Kreislauf-Forschung (DZHK) | Jenscare Scientific | P+F Products + Features | Sint Antonius Ziekenhuis (investigator-initiated) |
| Plannend sample size, n | 300 | 870 | 360 | 150 | 200 | 150 |
| Device | TriClip T-TEER system | PASCAL T-TEER system | T-TEER, TTVA | LuX-Valve Plus TTVR System | CAVI (TricValve) | T-TEER (TriClip or PASCAL) |
| Design | T-TEER vs OMT | T-TEER vs OMT | TTVI vs OMT (2:1) | Single arm | CAVI vs OMT | T-TEER vs OMT (2:1) |
| Follow-up | 2-y follow-up | 2 y | 1 y (and yearly up to 3 y) | 30 d and yearly up to 5 y | 1 y | 1 y |
| Primary endpoint | Milton Packer clinical composite score | All-cause death<br>HF hospitalization<br>QoL improvement | All-cause death<br>HF hospitalization | Major adverse event (MAE) at 30 days | All-cause mortality, Alternate TV therapy (transplant, RVAD, TV surgery or percutaneous therapy)<br>Annualized rate of a significant HF encounter<br>Improvement in KCCQ of ≥10 points | Mortality and hospitalizations for HF, and improved QoL |

CAVI = caval valve implantation; CLASP II TR = Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial; OMT = optimal medical treatment; QoL = quality of life; RVAD = right ventricular assist device; TRICAV = TRIcvalve biCAVal Valve System for Severe Tricuspid Regurgitation; TRICI-HF = TRICuspid Intervention in Heart Failure Trial; TRINITY = A Study to Evaluate the Safety and Performance of LuX-Valve Plus System for Tricuspid Replacement; T-TEER = transcatheter tricuspid edge-to-edge repair; TTVA = transcatheter tricuspid annuloplasty; TTVR = transcatheter tricuspid valve replacement; TV = tricuspid valve; other abbreviations as in Tables 2 and 3.

Europe and the United States, the therapy may rapidly expand to patients with expected suboptimal TR reduction after T-TEER (residual TR ≥2+). However, TTVR is associated with specific challenges that need to be anticipated when selecting the most appropriate therapy for an individual patient. Future research will also aim at determining whether relevant differences exist between the various TTVR devices currently under investigation.

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**KEY WORDS** **echocardiography, emerging technologies and innovations**

**APPENDIX** **For a supplemental table, please see the online version of this paper.**