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# Assessment and procedural guidance with echocardiography for transcatheter tricuspid regurgitation devices☆

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ABSTRACT

Echocardiographic imaging is an integral part of characterizing patients with tricuspid regurgitation (TR) and helps in determining the timing of intervention and procedural guidance for transcatheter interventions. The rapid advances in both two-dimensional and three-dimensional imaging however have facilitated the development and deployment of novel transcatheter devices to address the unmet need for patients with symptomatic severe TR.



**Contents**



Transcatheter device treatment of severe, symptomatic tricuspid regurgitation (TR) has become a focus of innovation in recent years following a multitude of studies showing the effect of secondary TR on outcomes[1–4] and the high in-hospital mortality associated with isolated tricuspid valve (TV) surgery.[5,6] Conformité Européene (CE) Mark approval in 2018 for treatment of TR with the Cardioband device (Edwards Lifescience, La Jolla, CA) as well as the explosion of early feasibility trials for TR devices in the United States, is further evidence of the public and scientific attention to this disease. Transcatheter TV devices currently under investigation or development involve not only devices with a surgical predicate, but also novel approaches to both annular reduction and leaflet coaptation. Because the devices must be implanted without the benefit of direct visualization, imaging of the TV has become a major determinant of technical success. Although multi-modality imaging is frequently required for procedural planning, this manuscript will focus on the echocardiographic assessment of the anatomy and function of the TV which may determine device choice, and the important imaging views used for intra-procedural guidance.

## Pre-procedural imaging of the TV

Functional or secondary TR can be classified into the following 4 primary disease processes: (1) left-sided heart disease (valve disease or left ventricular dysfunction), (2) pulmonary arterial hypertension (i.e. chronic lung disease, pulmonary thromboembolism, left-to-right shunt disease, or idiopathic disease), (3) right ventricular (RV) disease or dysfunction (i.e. myocardial disease or RV ischemia/infarction), and (4) idiopathic TR which we now understand is related to progressive

*Abbreviations and acronyms:* 2D, two-dimensional; 3D, three-dimensional; CE, Conformité Européene; ICE, intracardiac echocardiography; PISA, proximal isovelocity surface area; RA, right atrial; RV, right ventricular; TEE, transesophageal echocardiographic; TR, tricuspid regurgitation; TV, tricuspid valve; ViV, Valve-in-Valve; VCA, vena contracta area.

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right atrial (RA) and RV dilatation related to other disease processes (i.e. atrial fibrillation, diastolic dysfunction).

In addition to describing TR by primary disease process, it is valuable to categorize functional TR by the predominant morphologic abnormality of the TV apparatus which may be more relevant for transcatheter device choice and can be imaged by echocardiography: (1) tethering or tenting of the TV leaflets and (2) dilatation of the annulus and/or RA/basal RV.[7] The first morphology, tethering of the TV leaflets, is associated with displacement of the papillary muscles thus resulting in inadequate chordal length to allow for leaflet approximation. Although annular dilatation is present, it is not the primary mode of TR. Leaflet tethering is most common with significant pulmonary hypertension (which results in mid-RV dilatation and papillary muscle displacement) and left heart disease (which results in septal displacement and tethering of the septal leaflet). A varying degree of RV dysfunction may accompany RV remodeling depending on the severity of the primary disease process.

The second morphology of functional TR, annular dilatation, results in insufficient leaflet coverage of the annular orifice and is associated with idiopathic functional TR. Annular devices thus would seem most appropriate for cases where annular dilatation is the predominant lesion and less effective in patients with marked leaflet tethering. In fact, predictors of recurrent TR following surgical annular repair include echocardiographic measurements of tricuspid valve tenting height >0.76 cm or tenting area >1.63 $cm^2$.[8,9] Other relevant anatomic considerations for transcatheter device therapy are listed in Table 1.

Although echocardiography is the test of choice for assessing the severity of TR, there are significant limitations of the current recommendations[10] which have been highlighted in a recent review.[11] Importantly, the color Doppler parameters typically used to assess mitral regurgitation cannot be easily translated to the lower pressure right heart and the TV. In addition, the unique anatomy of the TV with the long anterior and septal leaflet coaptation line,[7] frequently results in a slit-like regurgitant orifice that cannot be accurately assessed using the assumptions of the proximal isovelocity surface area (PISA) method. Quantitative Doppler methods as well as three-dimensional (3D) color Doppler direct planimetry of the vena contracta area (VCA) may be useful adjuncts to the 2D PISA method[12] and have been used in clinical trials.[13,14] A recent comparison of the three quantitative methods[15] showed that 2D PISA regurgitant orifice area correlates with 3D-VCA and quantitative Doppler methods but significantly underestimates the severity of TR in nearly a third of patients. Finally, this study confirmed findings of prior studies[16–18] showing that different cutoffs for severe TR should be used for each method: 2D PISA method ≥0.34 $cm^2$, 3D-VCA ≥0.60 $cm^2$ and quantitative Doppler ≥0.65 $cm^2$.

Because patients with TR present with non-specific symptoms until late in the disease when right heart failure occurs, the current echocardiographic guidelines grading categories of mild, moderate and severe, do not adequately categorize patients requiring intervention.[10,19] A new grading scheme for TR comprising five grades has recently been proposed to extend the current three grade scheme, which does not provide adequate differentiation at the upper end of the severity scale, introducing grades of "severe", "massive", and "torrential" TR.[20] Recent studies have suggested that the additional grades are not only useful in determining device efficacy[14] but may also be associated with worse outcomes.[21] Further studies, in particular using different cross-sectional three-dimensional imaging modalities such as cardiac MRI and computed tomography, are required to validate the use of the new grading classification.

**Table 1**
Anatomic considerations for surgical or transcatheter interventions.
Reproduced with permission from Dahou A, Levin D, Reisman M, Hahn RT. Anatomy and Physiology of the Tricuspid Valve. JACC Cardiovasc Imaging 2019;12:458–468.

| Tricuspid leaflets and commissures | Interventional considerations |
|---|---|
| • Large valve orifice (7–9 $cm^2$, with mean gradient <2 mmHg | • Stenosis is unlikely with central orifice devices (i.e. Edge-to-edge repair or spacer devices) however mean gradients of >2–3 mmHg may be significant. |
| • Usually 3 leaflets but variable (up to 6) or with deep clefts and folds | • Imaging leaflet anatomy may be challenging |
| • Very thin, translucent leaflets | • Imaging leaflet anatomy challenging<br>• Leaflets may not be ideal for anchoring devices |
| • Anterior leaflet is typically the largest, with the greatest motion | • High leaflet stress with greater leaflet motion |
| • Septal leaflet may be short radially, and is the least mobile | • Maneuvering to capture this leaflet may be difficult |
| Chordae and papillary muscles | Interventional considerations |
| • Anterior papillary muscle is largest, supplying chordal support to the anterior and posterior leaflets | • Anterior papillary muscle serves as an imaging landmark for these leaflets |
| • Septal leaflet chordae insert directly into septum or with multiple, small papillary muscles | • "Tenting" or tethering of the septal leaflet is common etiology of secondary TR, particularly if the septum is displaced toward the left ventricle |
| • Average of 25 chordae with varying configurations composed of straight collagen bundles (thus less distensible than mitral chordae) | • Chordae may interact with catheters and devices.<br>• Marked tethering results from dilatation of the right ventricle or displacement of papillary muscles |
| Tricuspid annulus | Interventional considerations |
| • D-shaped and flat along the septum | • Dilatation in disease states occurs along the unsupported lateral and posterior free wall portion of the annulus with more planar, circular shape. |
| • Dynamic (larger in end-systole, early diastole, and atrial systole) | • Dynamic changes in shape must be accounted for with device design |
| • Average perimeter = 12 ± 1 cm<br>Average area = 11 ± 2 $cm^2$ | • In the setting of dilatation, large annular devices may be required |
| • Heterogeneity in muscle and fatty tissues with discontinuous fibrous support | • Stability of annular anchoring systems may vary along the circumference of the annulus |
| Structures adjacent to the tricuspid valve | Interventional considerations |
| • Right atrium is thin-walled, markedly dilated in advanced disease | • Large space to maneuver devices but more difficult for imaging |
| • SVC = mean length ~7 cm, maximum diameter ~2 cm, irregular in shape<br>• IVC = largest vein in the body (normally <21 mm) | • Venous access considerations for new devices may be limited by SVC diameters and non-linear shape. IVC--annular angle may pose issues for device placement |
| • Coronary sinus enters right atrium at the commissure between the septal and posterior leaflet | • Inflow of the coronary sinus is a good anatomic marker of this commissure |
| • No continuity between inflow and outflow | • Little risk for outflow tract obstruction |
| • Right coronary artery within the AV groove (variable transverse distance from annulus) | • Short (~3–4 mm) transverse distance along the inferior annulus (adjacent to the posterior leaflet) |
| • Atrioventricular node (AVN), Bundle of His crosses the septal leaflet attachment 3 to 5 mm posterior to the anteroseptal commissure | • Risk for heart block with devices in this region |
| • Noncoronary sinus of Valsalva borders the anterior/superior annulus (commissure between the noncoronary/right coronary sinuses adjacent to the septal/anterior tricuspid leaflet commissure) | • Risk for perforation with devices in this region<br>• Aortic sinuses of Valsalva may be used as an anatomic marker for the septal-anterior commissure |

## Intra-procedural echocardiographic imaging

Transesophageal echocardiographic (TEE) imaging of the TV is more difficult than the mitral valve for a number of reasons. First, the TV leaflets are remarkably thin with a variable number of leaflets and/or folds, extensive chordal system and larger annular area.[7] Second, from the mid-esophageal plane, the TV is in the imaging far-field with left heart structures between the TEE probe and the valve. Thus any cause of acoustic noise or attenuation (i.e. calcified left heart valve, bioprosthetic material) will reduce image quality to visualize the TV. Finally, the anatomic position of the thoracic esophagus does not allow co-axial imaging of the tricuspid annular plane requiring the use of lateral resolution to image the thin leaflets.

There are a number of solutions to these imaging issues. First, because the inferior border of the right heart is adjacent to the diaphragm, insertion of the probe to the distal esophagus creates an imaging plane with no left heart structures in view (Fig 1). The distal esophageal position of the probe also reduces the depth of field for imaging the TV bringing the leaflets into the near field. In addition to the imaging levels advocated by the American Society of Echocardiography TEE guidelines,[22] the distal esophageal view has become a standard imaging plane for TV assessment.[12]

The transgastric views on TEE also allow for unobstructed imaging of the TV. This view is particularly important for imaging the coaptation zone in short-axis for the identification of number/location of leaflets, commissures, chordae and papillary muscles (Fig 2A) The transgastric views are particularly important for device implantation including orientation and position of the edge-to-edge device (Fig 2B, C), and anchor position for various annular devices as well as the apically-anchored spacer device.[23–25]

## Three-dimensional echocardiography

Because of the complex and varied anatomy of the TV, 3D TEE is an essential imaging tool with multiple modes of acquisition and display[26] that are particularly useful for imaging the TV (Fig 3). Any 3D imaging mode is associated with reduced temporal and spatial resolution compared to 2D imaging so the imager must determine the most appropriate mode for any given task. Real-time imaging includes simultaneous two-dimensional (2D) biplane imaging (Fig 3A) and narrow-angled (Fig 3B) or user-defined 3D volumes (Fig 3C). Gated 3D modes, with or without (Fig 3C) color Doppler, allow acquisition of larger volumes by splicing together multiple subvolumes generated by sequential R-R cycles. Despite the presence of atrial fibrillation, systolic time intervals remain relatively constant and allow the performance of multi-beat spliced 3D acquisition resulting in improved spatial and temporal resolution.

Simultaneous 2D-TEE biplane imaging is particularly helpful for imaging the TV from the mid and deep esophageal levels. As a 3D matrix probe function, spatial and temporal resolution is not as good as single plane imaging however the additional orthogonal imaging plane, which can be manipulated from the primary imaging plane, is an essential tool for device guidance and to understand mechanism of TR. One of the most important primary views for biplane imaging is the 60° RV inflow-outflow view, also referred to as the TV commissural view since the septal leaflet coaptation line spans the annular plane from this view. Simultaneous multiplane imaging can be used to scan across the valve; starting near

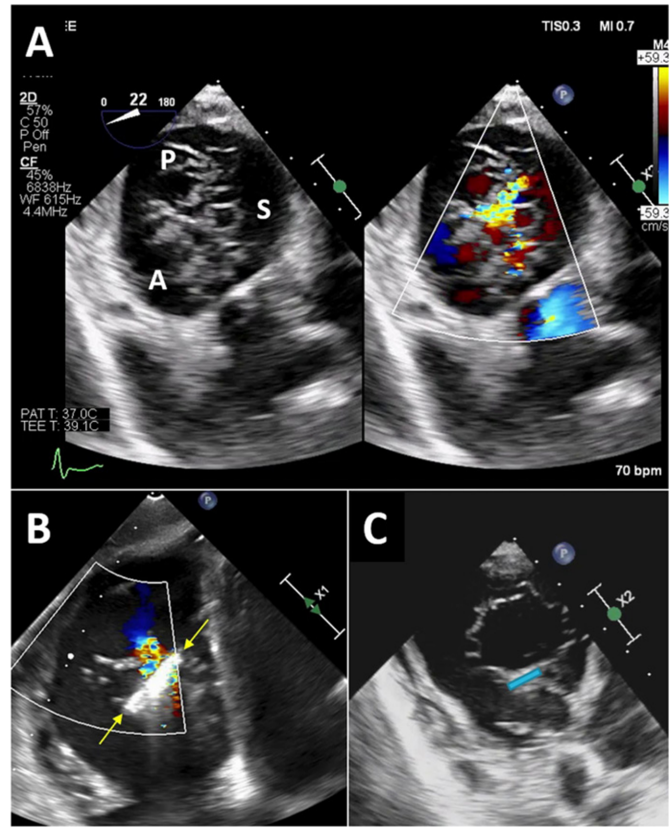


**Fig 2.** Transgastric views: The transgastric views allows for unobstructed imaging of the tricuspid valve coaptation zone in short-axis. Panel A shows the simultaneous multiplane short-axis view of the tricuspid valve for the identification of number/location of leaflets and commissures, as well as the location of the regurgitant jet. Panel B shows a tricuspid edge-to-edge device orientation and position (yellow arrows). Following implantation of the device (Panel C, blue line) a tissue bridge results in the creation of a double orifice. Abbreviations: A = anterior leaflet, P = posterior leaflet, S = septal leaflet.

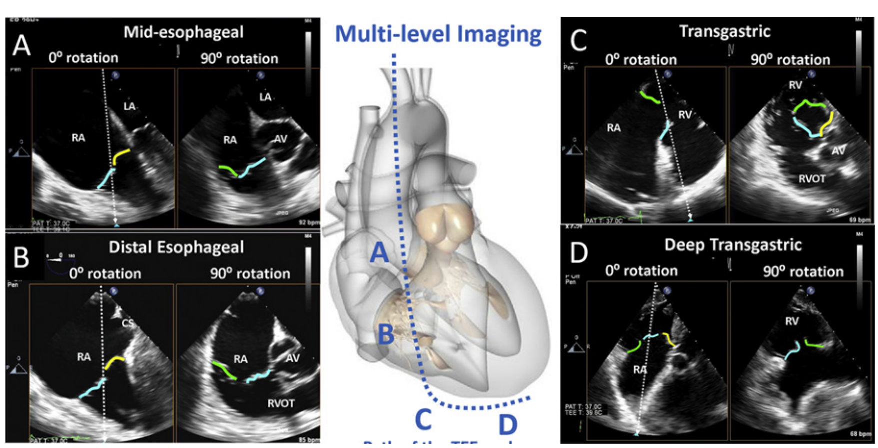


**Fig 1.** Multi-level imaging of the tricuspid valve. The path of the esophagus allows for multi-level imaging of the tricuspid valve, starting with the mid-esophageal level (panel A) which images the right heart in the far field. The distal esophageal view (panel B) brings the probe closer to the tricuspid valve with no intervening left heart structures. Because the valve is positioned just superior to the diaphragm, the transgastric views (both shallow transgastric in panel C, and deep transgastric in panel D) also image the tricuspid valve and right heart in the near field.

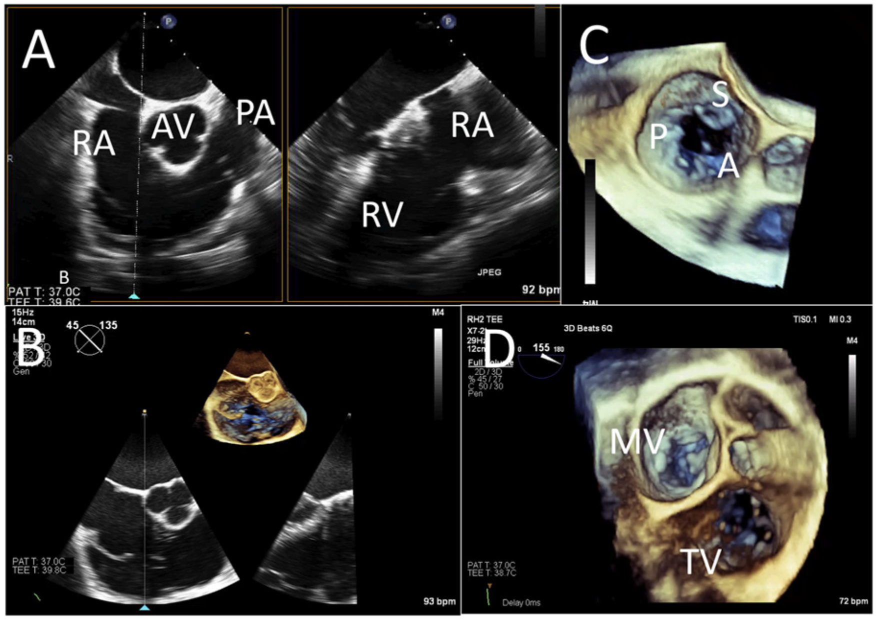


**Fig 3.** Three-dimensional imaging modes. Multiple three-dimensional imaging modes can be used depending on the goals of imaging. Simultaneous biplane imaging (panel B) particularly in the right ventricular inflow-outflow view can identify leaflet coaptation regions. Narrow volume real-time imaging (panel B) maximizes temporal resolution but sacrifices a wide field of view. User-defined single-beat volumes can be oriented to image the tricuspid valve in the cardiologist's en face view (panel C) with the anterior leaflet at 6 o'clock. A full volume multi-beat acquisition (panel D) allows for very large volumes to be acquired with good temporal resolution (volume rate of 29 Hz in this example).

the aorta, the anterior-septal coaptation zone is imaged and toward the lateral wall, the posterior-septal coaptation zone is imaged.

In addition to the acquisition modes, there are a number of ways to display the 3D images.[26] The three broad categories of display are: surface rendering, volume rendering and 2D multi-planar images. The most commonly used display for intra-procedural guidance are volume rendering and multi-planar imaging which can be performed simultaneously as volume rendering plus either simultaneous biplane images, or 3 orthogonal planes (Fig 4A). Typically, the additional 2D images could not be manipulated, however recent advances in software and hardware now allow for real-time 3D multiplanar reconstruction. With this mode three orthogonal planes can be manipulated during live-scanning (Fig 4B). This mode is particularly helpful for precise alignment of the native anatomy or devices.

An adequate field of view to include adjacent anatomy helps with leaflet identification; the aortic valve/aorta is adjacent to the anterior leaflet, and the interatrial septum/mitral valve adjacent to the septal leaflet with the coronary sinus identifying the commissure between the septal and posterior leaflets. Although the American Society of Echocardiography 3D guidelines[26] recommend orienting the 3D volume in a "surgeon's view" with the interatrial septum at 6 o'clock, interventionalists and imagers guiding TV procedures prefer to image the valve in the "cardiologist's view" with the anterior leaflet at 6 o'clock (Fig 2C).[24] The advantage to this 3D en face orientation is the similarity of leaflet position on the image to the transgastric view.

## Specific transcatheter TV devices

Current transcatheter TV devices (Fig 5) can be divided into those treating annular dilatation (i.e. Trialign, Cardioband, TriCinch, Millipede, Cardiac Implants), those directly affecting leaflet coaptation (i.e. MitraClip, PASCAL, FORMA), heterotopic valve implantation (i.e. Cavi, Tricentro) and transcatheter TV replacements (i.e. Navigate, Trisol, Valve-in-Valve [ViV]). Intra-procedural imaging for these devices has recently been reviewed with a summary of key images in Fig 6.[23]

A growing interest in the use of intracardiac echocardiography (ICE) for structural heart disease procedures stems in part from the accepted

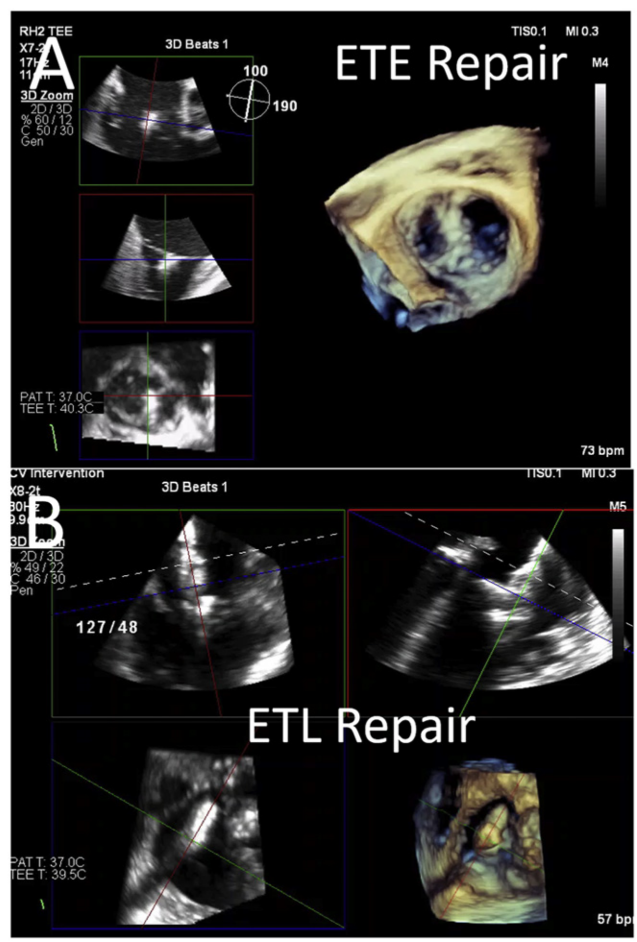


**Fig 4.** Three-dimensional rendering. Volume rendering allows for an appreciation of the three-dimensional anatomy however without a loss of temporal or spatial resolution, current machines can display simultaneous two-dimensional and three-dimensional images (panel A). In addition, newer software packages allow manipulation of the two-dimensional images during real-time image acquisition.

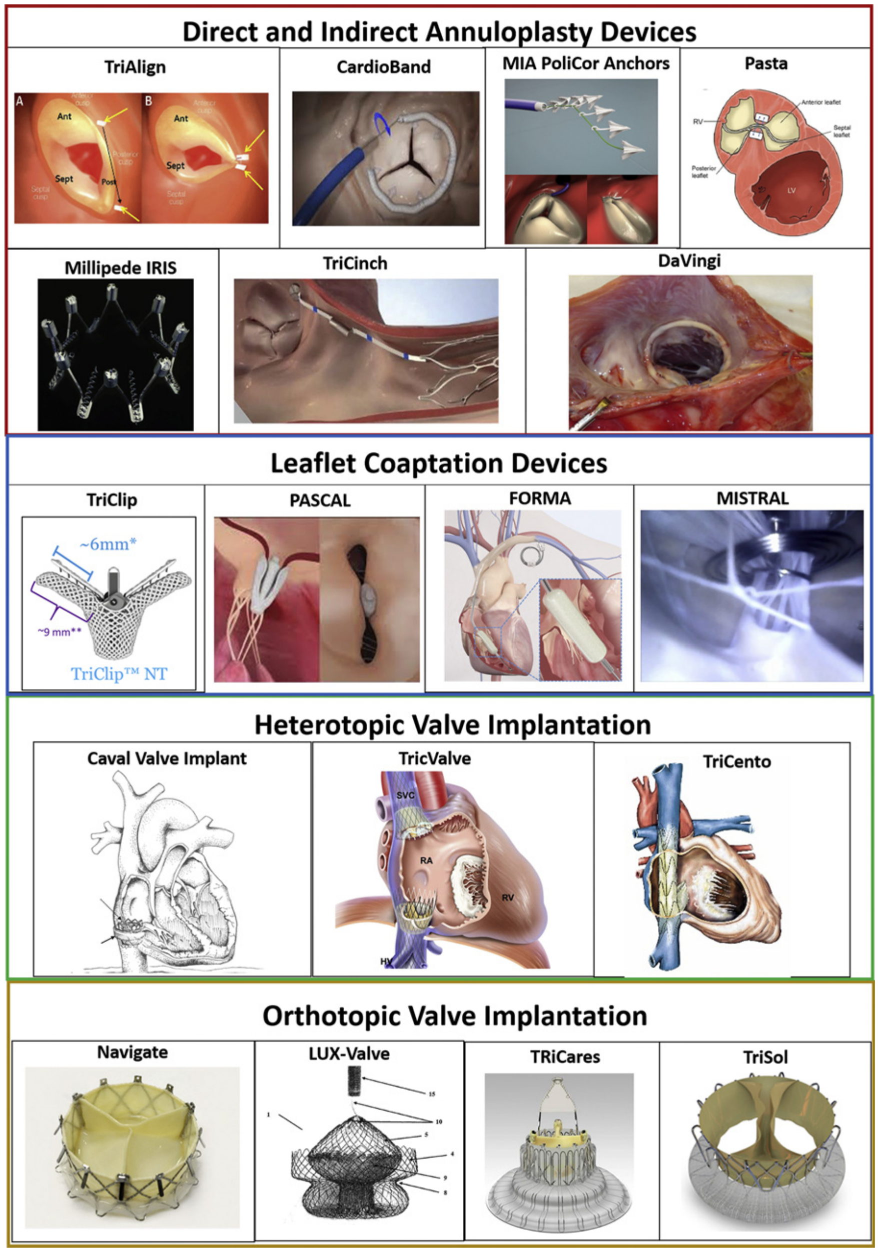


**Fig 5.** Transcatheter devices to treat tricuspid valve regurgitation. Transcatheter tricuspid valve devices can be categorized into direct and indirect annular repair devices, leaflet coaptation devices, heterotopic valve implantations and orthotopic transcatheter tricuspid valve replacements.

use of ICE as an alternative to TEE for imaging transcatheter closure of interatrial communications and the desire to simplify the procedures and eliminate general anesthesia.[27,28] The use of ICE imaging for transcatheter TV procedures is fueled by the limitations of imaging the TV, previously mentioned, but also by the problems of shadowing of the native anatomy by large device sheaths and catheters. ICE imaging is an attractive alternative with direct access to the right heart however a steep learning curve must be overcome and the added cost of the single-use catheter is discouraging particularly since the complex TV procedures are unlikely to be performed under conscious sedation. The development of three-dimensional ICE catheters may improve the utility of ICE for structural heart procedures[29] however current probes remain limited in spatial and temporal resolution.

## Conclusion

Echocardiographic imaging is an integral part of characterizing patients with TR and helps in determining the timing of intervention and procedural guidance for transcatheter interventions. The rapid advances in both two-dimensional and three-dimensional imaging however have facilitated the development and deployment of novel transcatheter devices to address the unmet need for patients with symptomatic severe TR.

## Statement of conflict of interest

Dr. Hahn reports speaker fees from Boston Scientific Corporation and Baylis Medical; consulting for Abbott Structural, Edwards Lifesciences, Medtronic, Navigate, Philips Healthcare and Siemens Healthcare; non-financial support from 3mensio; and is the Chief Scientific Officer for the Echocardiography Core Laboratory at the Cardiovascular Research Foundation for multiple industry-sponsored trials, for which she receives no direct industry compensation.

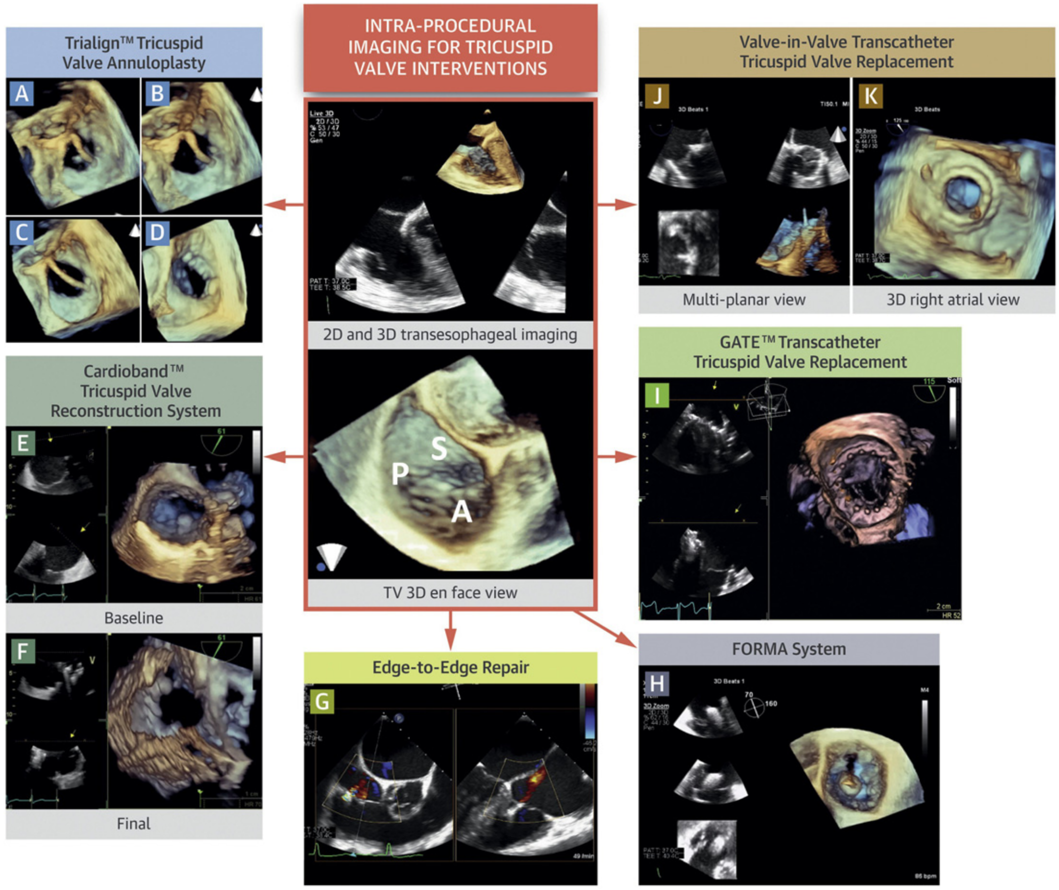


**Fig 6.** Intra-procedural imaging for transcatheter tricuspid valve devices. Intraprocedural imaging for various devices currently under investigation relies heavily on 2-dimensional (2D) and 3-dimensional (3D) echocardiography for guidance. The 6 procedures reviewed exemplify some of the imaging successes and challenges in this field: (A to D) Trialign; (E, F) Cardioband; (G) the edge-to-edge leaflet repair; (H) the FORMA device; (I) GATE transcatheter replacement device; and (J, K) transcatheter tricuspid valve-in-valve procedure. Reprinted with permission from Hahn RT, Nabauer M, Zuber M et al. Intraprocedural Imaging of Transcatheter Tricuspid Valve Interventions. JACC Cardiovasc Imaging 2019;12:532–553.

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