

Imaging in transcatheter native mitral valve replacement with Tendyne mitral valve system: echocardiographic pathway for the interventional imager

Correspondence: Prof. Domenico Galzerano, MD, FESC, FEACVI, The Heart Centre, King Faisal Specialist Hospital and Research Center, Riyadh and College of Medicine, Alfaisal University, MBC-16, PO Box 3354, Riyadh 11211, Saudi Arabia. Tel. +966.0112162919 #45195; Mobile +966.539037762; +39.328.4157343. E-mail: domenicogalzerano@libero.it; dgalzerano@alfaisal.edu; dgalzerano@kfshrc.edu.sa

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¹Heart Centre, King Faisal Specialist Hospital & Research Centre, Riyadh, Saudi Arabia; ²Cardio Center "De Gasperis", Niguarda Hospital, Milan, Italy; ³Cardiology Division, Cardarelli Hospital, Naples, Italy; ⁴College of Medicine, Alfaisal University, Riyadh, Saudi Arabia

Abstract

The interaction between the implanter team and the imager team is critical to the success of transcatheter native mitral valve replacement (TMVR), a novel interventional procedure in the therapeutic arsenal for mitral regurgitation. This imaging scenario necessitates the addition of a new dedicated professional figure, dubbed "the interventional imager," with specific expertise in structural heart disease procedures. As its clinical application grows, knowledge of the various imaging modalities used in the TMVR procedure is required for the interventional imager and beneficial for the interventional implanter team. The purpose of this review is to describe the key steps of the procedural imaging pathway in TMVR using the Tendyne mitral valve system, with an emphasis on echocardiography. Pre-procedure cardiac multimodality imaging screening and planning for TMVR can determine patient eligibility based on anatomic features and measurements, provide measurements for appropriate valve sizing, plan/simulate the access site, catheter/sheath trajectory, and prosthesis positioning/orientation for correct deployment and predict the risks of potential procedural complications and their likelihood of success. Step-by-step echocardiographic TMVR intraoperative guidance includes: apical access assessment; support for catheter/sheath localization, trajectory and positioning, valve positioning and clocking; post deployment: correct clocking; hemodynamic assessment; detection of perivalvular leakage; obstruction of the left ventricular outlet tract; complications. Knowledge of the multimodality imaging pathway is essential for interventional imagers and critical to the procedure's success.

Introduction

Mitral regurgitation (MR) is the most prevalent form of valve disease in subjects >75 years of age in the Western world [1,2] and the second-most frequent valvular heart disease in Europe and it is associated with high morbidity and mortality [1-3]. Mitral regurgitation represents an important health care burden



and its treatment is still a challenge in clinical arena [3,4]. Mitral valve (MV) surgery plays a primary role on indications for intervention, however, transcatheter procedures have emerged as an alternative option to treat inoperable and high-risk surgical patients and have been impressively expanding [3,4-15].

This growth has been possible thanks to the developments and rapid progress of new percutaneous devices but also due to the innovations in imaging techniques [4-15,16-24]. These developments have prompted the need for a new dedicated professional figure with specific competencies in the field of structural heart disease procedures imaging 'the interventional imager' whose collaboration with the implanter team is crucial for the procedural success [22,25,26].

Nowadays interventional imaging is an emerging field of expertise whose development has been mandated by rapid advances in percutaneous technologies in the treatment of structural heart pathologies.

The transcatheter edge-to-edge mitral leaflet repair transcatheter edge to edge repair (TEER) is the most frequently applied interventional procedure in MV therapeutic strategy, however, some anatomic substrates are not suitable (e.g., cleft or perforation, previous mitral valve repair, mitral annulus calcification, leaflet thickening and calcification in particular in the grasping areas, short posterior mitral leaflet with limited motion, rheumatic heart disease) as well as the repair is not always able to both fully correct the severity of the regurgitation and prevent MR progression overtime [3,5-15]. Transcatheter native mitral valve replacement (TMVR) is a novel procedure that has the potential to overcome some of the current limitations associated with the transcatheter edge-to-edge mitral valve repair technique [4-15]. Imaging is paramount in planning and guide the MV interventional procedure. While the angiography and the fluoroscopy are performed by the implanter team, other multimodality imaging, semi and non-invasive, the so called 'interventional imaging', is performed by the structural heart disease interventional imagers [16-22,25,26]. A peculiar imaging work-up is essential to select the right patient [16-22,25,26].

In this setting, computed tomography (CT), two- (2D) and three-dimensional (3D) transesophageal echocardiography (TEE) have a key role in multimodality imaging and in the interaction between the implanting and imaging teams [17-20]. As its use is expanding into the clinical arena, a detailed description of the use of different imaging modalities is necessary for the interventional imager and is also advised for the interventional implanter team.

Nowadays there is a wide range of TMVR devices at various stages of development [5-15,27-29]. We will focus our review on the Tendyne valve, the most employed TMVR device for native anatomy that is a Conformitè Européenne (CE) mark [27,28] approved transcatheter mitral valve device designed to be implanted using a transapical approach. It is repositionable and retrievable and available in a large number of sizes [6-15,27-29]. Initially feasible for MR in ongoing investigations is showing promising results also in the setting of mitral annular calcification and mixed disease [5-15,27-30]. The results for the 100 first patients included in the early feasibility study and at 2 years have showed optimal results on MR reduction [27,28]. In the Expanded Clinical Study of the Tendyne Mitral Valve System (NCT02321514) the impact of TMVR on severity of MR, reduction in Heart failure hospitalization rate and improvement in symptoms was sustained through 2 years [28]. The SUMMIT trial, The Tendyne Mitral Annular Calcification Study and the Resolve - MR trial (ClinicalTrials.gov Identifier: NCT04818502) are currently underway and will provide further insights regarding safety and efficacy of novel transcatheter MV replacement systems [5-15,28,29].

Aim

The aim of our review paper is to provide a focused update, as it pertains to the interventional echocardiographer, of the key steps of the procedural imaging pathway in TMVR with the Tendyne mitral valve system (Abbott, Menlo Park, CA, USA) emphasizing potential caveats and areas of difficulty.

TMVR with Tendyne

The Tendyne system consists of two self-expanding nitinol frames and a trileaflet porcine pericardial valve. The prosthesis is inserted using a transapical approach via a left minithoracotomy and is secured in a stable position after deployment by means of a braided, high-molecular-weight polyethylene tether, which is attached to an apical epicardial pad. Imaging work up comprises: baseline evaluation of MR, preprocedural screening and procedure planning, intraprocedural guidance and monitoring and assessing and following over time the results of the procedure (Figure 1) [5-9,17-19].

Baseline evaluation of MR, preprocedural screening and procedure planning

The current European Valvular Heart Disease Management guidelines [3] give Class IIB recommendations for transcatheter mitral valve repair in symptomatic patients with severe primary MR despite optimal medical therapy, reasonable life expectancy but prohibitive surgical risk and Class IIA recommendations for symptomatic patients with severe secondary MR fulfilling the anatomical inclusion criteria who are not eligible for surgery. In high-risk symptomatic patients without concomitant coronary artery or other cardiac disease requiring treatment ,not eligible for surgery and not fulfilling the criteria suggesting an increased chance of responding to TEER, the Heart Team may consider in selected cases a TEER procedure or other transcatheter valve therapy if applicable, after careful evaluation for ventricular assist device or heart transplant

Currently, the use of the Tendyne Mitral Valve System is indicated for treatment of the native mitral valve without prior mitral valve intervention in patients with moderate-to-severe or severe mitral valve regurgitation (MR grade $\geq 3+$), left ventricular ejection fraction (LVEF) \geq 30%, left ventricular end-diastolic dimension (LVEDD) \leq 7.0 cm, who do not have severe mitral annular calcification and are deemed not suitable for surgical repair or replacement by a multi-disciplinary heart team who have: primary MR and are at prohibitive surgical risk, deemed not suitable for transcatheter repair by a multidisciplinary heart team and have left ventricular end-systolic dimension (LVESD) >3.0 cm, or secondary MR and are symptomatic despite maximally tolerated guideline directed medical therapy (including cardiac resynchronization therapy, if indicated); also mixed mitral stenosis and regurgitation is considered acceptable as indication [5-15].

In fact, given the heterogeneity and complexity of mitral valve pathological lesions, some patients do not meet the eligibility criteria for TEER in order to predict an effective repair



(rheumatic etiology, endocarditis-related valve disease, prior MV surgery, cleft or perforated mitral leaflets, posterior leaflet length <7 mm, presence of severe calcifications in the grasping area, trans valvular mitral pressure gradient >4 mmHg or MV area <3.5 cm²) [5-21]. In these anatomical scenarios the TMVR is less invasive than mitral valve surgery and it has the potential to overcome some of the anatomical limitations of TEER [5-15]. Multimodality imaging work-up is essential to select the right patient and TEE and fluoroscopy imaging are keys for guiding the procedure (Figure 1).

Baseline imaging screening in TMVR is the recommended imaging pathway of MR assessment [4,30] and it has to carefully evaluate the etiology, mechanisms and severity of MR as well as the association of any degree of mitral stenosis or any other valvular abnormality and annular calcification and its extension. Peculiar pre-procedure cardiac multimodality imaging for TMVR is able to determine patient eligibility according to the anatomic characteristics and measurements, to provide information for appropriate valve sizing and to detect features that can predispose to potential hazard or complications and contraindications [5-22].

In the preprocedural assessment, cardiac CT plays a major role allowing to size the left ventricle and the MV annulus, to detect and score the MV apparatus calcification and to simulate the prosthesis implantation and neo-left ventricular outflow tract obstruction (LVOT) dimensions, hence predicting the risk of LVOT obstruction [31-38]. Echocardiography is useful in in diagnosing contraindications (left atrial appendage or left ventricular clot, endocarditis, large or small annulus size, thin or fragile apex, not suitable for apical puncture) and in the assessment of the anatomical features that can help in predicting potential procedural complications [16-21].

Among the possible complications, the post implantation LVOT obstruction is one of the most important. In fact, implantation of a device can result in LVOT obstruction as the Tendyne valve frame may project into the left ventricular cavity and the LVOT. Considering that in the neo LVOT, the new device and the anterior mitral leaflet and the LVOT are actors interplaying in a new dynamic structure, factors that predispose to LVOT obstruction include all the above structures. A long anterior leaflet, a hypertrophied interventricular septum, a small left ventricle (LV) size and an aorto-mitral angulation of <110° can predict potential risks. In addition, we have to consider that LV obstruction can either be fixed or dynamic. Fixed LVOT obstruction occurs when the prosthetic mitral valve pushes the anterior mitral leaflet toward the interventricular septum, thus determining a narrower neo-LVOT. Dynamic LVOT obstruction determine the dynamic systolic anterior movement, the anterior mitral leaflet toward the interventricular septum caused by Bernoulli forces generated in the neo-LVOT [16-21,31-40].

Echocardiographic imaging

In addition to the baseline recommended MR assessment [4,30], additional peculiar imaging features are required in the preprocedural screening and planning for TMVR in order to assess the anatomic suitability and the potential procedural risks (Figure 1) [16-21]. These additional echocardiographic features can be schematized as follow:

Left ventricle

LV 2D image quality assessment: a good quality of the acoustic window and in particular of the long axis and commissural TEE view, key for the intraprocedural guidance, is fundamental; *LV siz-ing*: LV has to be measured by TEE in the 3-chamber view or the short axis view along the septal-lateral direction; it has been reported that left ventricular end diastolic diameter (LVEDD) <3.5 cm or LV end systolic volume (ESV) <12 ml/m² /BSA and therefore a small chamber sizes may raise potential procedural problem dealing with positioning and stability of the bioprosthetic valve; LV diastolic dimension more than 7 cm also is a contraindication.

LV morpho-geometry: with assessment of papillary muscle and chordae tendinae disposition; the location of the papillary muscles has to be imaged in order to avoid their potential damaging in the access and their interference with the procedure; apical location of the papillary muscle may interfere with the transapical access and the detection of an anterior displacement of the papillary muscle with consequent abnormal course of the chordae and/or aberrant chordae tendinae can make it more difficult to obtain the correct catheter trajectory and may increase the risk of LVOT obstruction.

LV thickness: an upper basal subaortic septal wall thickness >2 cm may increase the risk of LVOT obstruction; also septal thickness >1.5 cm can increase the risk of LVOT obstruction in presence of long anterior mitral leaflet (AML) and if the calculation of basal septal thickness x anterior M leaflet length is > 400 mm².

LVOT area: an LVOT area <1.8 cm increases the risk of LVOT obstruction in particular when associated with increased basal subaortic septal thickness and a long anterior mitral leaflet; -MV annulus to apex distance (diastole); when the distance is less than 100 mm is suggestive of potential procedural hazards; the assessment of the LVOT area and the MV annulus to apex distance are better assessed by CT scan.

Distance between the AML and IV septum in diastole less than 8 mm has also to be take in account as indicator of possible LVOT obstruction.

Left atrium

Left atrial (LA) dimensions: LA size <22 ml/m² is an indicator of potential procedural problems and suboptimal outcome.

Mitral valve apparatus

Annulus sizing: the septal-lateral, inter-commissural, inter trigonal dimensions and entire and posterior perimeter of the mitral annulus are important in order to decide the size of the valve to be implanted; TEE 3D enface view of the mitral valve (surgeon's view) is providing a reliable assessment also comparable to the CT annulus sizing. Using standard annular segmentation method acceptable ranges of size are considered the following: septal-lateral (SL) dimension: 25 to 42 mm, inter-commissural (IC) dimension: 35 to 48 mm, entire perimeter: 100 to 145 mm.

Anterior mitral leaflet: it has been reported that excessive length of AML may determine the potential hazard for LVOT obstruction. TEE long axis is the view of choice in assessing the AML length. A length >2.5 cm increases the potential risk of LVOT obstruction.



Calcium in the annulus and leaflets: the calcium in the annulus and leaflets is evaluated for potential hazards. Excessive calcium in the leaflets may be prohibitive without adjunct procedures such as balloon valvuloplasty to permit an optimal placement of the prosthesis. Calcium is better assessed by CT scan that also allows its scoring [23,29].

Aorto-mitral angle: a narrow angle <110° between LVOT/Aortic annulus and mitral annular planes predisposes to LVOT obstruction.

Cardiac computed tomographic imaging

Contrast-enhanced thin-sliced electrocardiography-gated cardiac CT (CCT) with three-dimensional reconstruction is considered to be fundamental for TMVR planning [5-10,23].

CT provides, with high spatial resolution, accurate LV and mitral annular sizing and LV geometrical assessment [5-10,16,23].

CT 3D sizing and procedural simulation is also performed in order to plan the optimal apical access site (Figure 2 A,B), the trajectory of the catheter/sheath, the positioning of the prosthesis for a correct deployment and the neo LVOT to prevent its obstruction and to predict the risk of potential procedural complications and their likelihood of success. CT reconstruction provides key information for:

- Chest and LV apical access
- Calcium in annulus
- LV, LA and MV annulus dimension for procedure feasibility and appropriate valve sizing
- simulation of prosthesis implantation and neo LVOT
- Thickness of myocardium and papillary muscle anatomy
- MV annulus to apex distance
- Implantation angles for best co-axiality
- anterior mitral leaflet length
- aorto-mitral angle
- septal bulge thickness

Intra-procedural guidance

After clinical decision making and preprocedural screening and planning, fluoroscopy and 2D and 3D TEE are key in the guidance of TMVR during the procedure [16-21].

The key step by step echocardiographic guidance for TMVR with the Tendyne system is illustrated in Figure 1 and Table 1 and is detailed described below.



TMVR= transcatheter mitral valve replacement, 2D= two dimensional, 3D= three dimensional, TTE= transthoracic echocardiography, TEE= transesophageal echocardiography, CT= computed tomography, MRI= magnetic resonance imaging, VHD= valvular heart diseases.

Figure 1. Algorithm for multimodality imaging of TMVR for the interventional imager.

Review



Apical access assessment

The site for optimal LV apical access that bisects the MV in both the commissural and septal lateral planes as planned by preprocedural CT (Figure 2 A,B) is assessed during the procedure using 2D TEE. Echocardiography allows imaging of the finger poke while pushing the apex. This is visualized as an outpouching with cystic appearance directed into the LV cavity (Figure 2 C,D). Echocardiographic imaging also allows to assess if the finger poke is matching the access point planned at preprocedural CT. It is important to use 2D TEE X-plane imaging on simultaneous bicommissural and LVOT views in order to perform a CT matching imaging (Figure 2).

Table 1. Echocardiographic imaging in transcatheter native mitral valve replacement with Tendyne system: intraprocedural guidance pathway.

Apical access assessment

Image finger poke

Access point planned in preprocedural CT matching

Catheter/sheath: trajectory, MV entanglement

- Monitoring and matching with planned trajectory

- Detect entanglement in MV apparatus
- Correct positioning of the wire and the delivery sheath through the mitral valve into the LA at A2/P2 in the mitral orifice

Valve orientation, deployment, LVOT assessment

- Positioning of the delivery system at the correct depth into the LA at A2/P2 in the mitral orifice
- Radial orientation (clocking): image when the valve is partially deployed, the outer anterior stent long cuff oriented on anterior MV annulus
 and the short three cuffs on the other sides
- LVOT obstruction

Post implant

- Prosthesis correct clocking- Hemodynamic assessment - Perivalvular leakage- LVOT obstruction

CT, computed tomography, MV, mitral valve; LVOT, left ventricular outlet tract; LA, left atrium; A2, medium A2 segment of anterior mitral leaflet; P2, medium scallop (P2) of posterior mitral leaflet.



Figure 2. Imaging in TMVR with Tendyne system. A,D) CT 3D X-plane optimal puncture site simulation in procedure plan; red dot, apex; green dot, optimal planned puncture site. A) CT long axis view. D) CT 2 chambers view; red arrow, apical finger poking. B,C) TEE 2D simultaneous 3 chambers, long axis view and 2 chambers commissural view; identification of the of the apical dimpling and finger poke outpouching in the LV (green arrow) matching with X-plane simulation in procedure plan; green dot, optimal planned puncture site. Post, posterior; Med, medial; LV, left ventricle; LA, left atrium.



Support for catheter/sheath localization, trajectory and positioning

Echocardiography can assess the appropriate advancement of the balloon-tip catheter from the LV into the LA ensuring that the catheter and the guidewire are matching the planned trajectory in preprocedural CT and are not entangled in the mitral subvalvular apparatus (Figure 3). To this aim, the catheter is moved in and out through the mitral valve apparatus ('flossing'). The wire/sheath monitoring is usually performed using 2D TEE, even though 3D imaging is useful to visualize the catheter position allowing its exact position inside the LV cavity. Enface 3D TEE surgical view is allowing the assessment of the correct positioning of the wire and the delivery sheath through the mitral valve into the LA at A2/P2 in the mitral orifice.

Guidance for valve positioning, orientation and clocking

The delivery sheath is inserted into the LV over the guidewire. An enface 3D TEE surgical view is used to position the delivery system at the correct depth into the LA at A2/P2 in the mitral orifice (Figure 4). The valve prosthesis is delivered through the sheath and partially deployed in the LA until the outer valve expands up to approximately three fourth of its final size in order to allow its orientation. The D-shaped outer stent or atrial cuff of the Tendyne prosthesis is extruded and then rotated to fit the anatomic shape of the native MV annulus (Figures 4 and 5). The radial orientation, 'valve clocking', is paramount for guidance. The outer frame of the bioprosthesis, designed to fit the mitral annulus, has to be aligned with the straight edge of the mitral annulus, oriented anteriorly against the aorto-mitral continuity. The anterior straight cuff/edge is the highest in comparison with the other edges and this feature allows the echocardiographers to detect it; the long cuff has to be placed on the straight anterior part of the annulus with the short cuffs on the other areas. 2D TEE X-plane imaging with simultaneous bicommissural and LVOT views is able to identify the higher anterior edge that, for an appropriately clocked valve, has only be visualized on the long-axis view of the aorta (Figure 5 A,B). If the long cuff is visualized in the commissural view on the medial or on the lateral position, the valve is not appropriately oriented but is medially or laterally clocked (Figure 5 C,D). Hence this imaging feature makes the interventional imager able to guide the implanter to rotate the bioprosthesis in the correct position. Although 2D TEE allows visualization of valve clocking on X-plane (Figure 6 A,B), in this phase 3D TEE assessment is crucial. In fact, 3D TEE surgeon's view of the MV confirms the bioprosthesis orientation and clocking and provides, by anatomical imaging, guidance for the implanter (Figure 6 C,D). After appropriate clocking, the valve prosthesis is withdrawn toward the LV and deployed intra-annularly (Figure 6 C,D). During implant, it is important to assess the position of the device in the LV to avoid LVOT obstruction. Even though a prediction of the impact of the size of the prosthesis into the LV is planned by preprocedural CT, a dynamic intraprocedural assessment is mandatory being the possible obstruction either fixed or dynamic. 2D TEE with pulsed wave (PW), continuous wave (CW) and color Doppler is the modality of choice in order to detect LVOT obstruction. Both 2D transesophageal and transgastric views are mandatory in order to detect any obstruction.



Figure 3. Wire imaging. A,B) 2D TEE X plane. A) correct wire trajectory and positioning in LV-LA; B) wrong wire trajectory directed posteriorly; the wire is directed posterior on the long axis view (yellow arrow). C) enface 3D TEE surgical view of the MV; D) simultaneous 3D view from the left atrium and the left ventricle of the MV orifice; correct trajectory and positioning of the wire into the LA at A2/P2 in the mitral orifice (red arrow).





Figure 4. Delivery sheath imaging. A) 2D TEE X plane; delivery sheath correctly positioned into LA at A2/P2 in the mitral orifice. B) 3D TEE live 3D: delivery sheath correctly positioned into LA at A2/P2 in the mitral orifice. C) An enface 3D TEE surgical view of the MV with zoom acquisition from above: the delivery system into the LA at A2/P2 in the mitral orifice. D) An enface 3D TEE surgical view with zoom acquisition from above: the delivery system into the LA at A2/P2 in the mitral orifice with the bioprosthesis inside its opening (red arrow). AO, aorta.



Figure 5. Imaging in TMVR with Tendyne system. A,B) The valve prosthesis, delivered through the sheath, partially deployed in the left atrium, until the outer valve expands up to approximately three fourth of its final size in order to allow its radial orientation; 2D TEE X plane, on simultaneous bicommissural and LVOT; partial extrusion of the Tendyne bioprosthesis for rotational orientation (yellow arrows) in the LA; correct clocking: long cuff oriented anteriorly on the aorta in the long axis plane (red brace B) the short cuffs on the other sides (green brace). C,D) TEE X plane, on simultaneous bicommissural and LVOT views; initial Tendyne device deployment and orientation: laterally clocked valve, long cuff is visualized anteriorly in the long axis (D) and laterally close to LAA in the bicommissural view (C). E) 3D surgical view: partial extrusion of the Tendyne bioprosthesis for radial orientation: laterally clocked valve, long cuff is oriented anteriorly and slightly laterally (red arrows).







Figure 6. Imaging in TMVR with Tendyne system. A,B) Final result after complete deployment; the Tendyne prosthesis fully extruded and correctly aligned anatomically in the LA. 2D TEE X plane without (A) and with color Doppler (B). Diastolic phase; normal opening of the prosthesis. C,D) 3D TEE surgeon's view of the MV imaging in two different perspectives; The D shaped outer stent, long cuff is aligned with the straight edge oriented anteriorly against the aortomitral continuity (blue braces); the 3D perspective allows to better visualize the position of the long (blue braces) and short (green braces) cuffs; red arrows, aortic-mitral continuity. TMVR, tanscatheter mitral valve replacement; TEE, transesophageal echocardiography; LVOT, left ventricular outlet tract; 2D, two dimensional; 3D, three dimensional; LA, left atrium; LV, left ventricle; LAA, left atrial appendage; Ao, aorta; MV, mitral valve.

Assessment after deployment

As the prosthesis can be repositioned or fully retrieved, it is important to assess after deployment: - the prosthesis correct clocking; - bioprosthesis functioning by hemodynamic doppler parameters (transvalvular gradients, pressure half time and valve prosthesis area) and residual intravalvular regurgitation; perivalvular leakage; -LVOT obstruction by transesophageal and transgastric views; due to the shielding of the prosthesis the correct alignment of the Doppler beam is difficult; -possible procedural complication including mitral prosthesis dislodgement, mitral annular rupture and pericardial tamponade.

Follow up imaging

Essential elements to assess during follow-up imaging of TMVR with Tendyne can be schematized as follow:

Device: assessment of device functioning and complication (dehiscence, dislodgement); presence of masses either vegetation or thrombi; infective endocarditis.

Hemodynamics: a careful assessment of transmitral gradients and the detection of the presence of residual intravalvular and perivalvular mitral regurgitation including the assessment of the pulmonary vein flow pattern; - Severity of tricuspid regurgitation and right ventricular systolic pressure

Chamber size and function: a comprehensive assessment of

left and right ventricular function and remodeling (dimensions, volumes) and the presence of pericardial effusion is mandatory.

Conclusions

The success of transcatheter native mitral valve replacement, a novel interventional procedure in the therapeutic armamentarium for mitral regurgitation whose use is expanding in clinical arena, relies on the interaction between the implanter team and the imager team. This new imaging horizon requires a dedicated professional figure with specific competencies in the field of structural heart disease procedures 'the interventional imager' whose collaboration with the implanter team is crucial. The knowledge of multimodality integrated imaging pathway in the different phases of TMVR is fundamental for the interventional echocardiographer to make an appropriate selection, to plan, to guide, and to assess outcomes and it requires mastery of all echocardiographic imaging modalities.

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