A New Transesophageal Echocardiography Guidance Protocol for Edge-to-Edge Repair of the Tricuspid Valve – The "Mainz-Approach"

Short title: New guidance protocol for TEER of tricuspid valve

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Abstract

Intraprocedural transesophageal echocardiography (TEE) guidance plays an essential role in transcatheter repair therapy of the tricuspid valve (TV). So far, several different imaging concepts are in use. However, an imaging protocol that fully addresses the morphological complexity of the TV and further offers efficacious workarounds for the frequently occurring restrictions of TV imaging is still missing. As a tertiary referral center with a large experience of more than 250 cases of transcatheter edge-to-edge repair (TEER) of the TV performed at the Heart Valve Center in Mainz/Germany, we have constantly adapted our periinterventional echocardiographic approach to accomplish both. As a key measure for success, we intensely rely on the transgastric acoustic windows that not only delivers high-resolution information on the morphology of the TV and all relevant procedural steps but also help to avoid the frequent shadowing artefacts experienced in transesophageal imaging.

Key Words: tricuspid valve; transcatheter; edge-to-edge; transesophageal; echocardiography; interventional imaging

Abbreviation list

TR	Tricuspid Regurgitation
TEE	Transesophageal Echocardiography
TEER	Transcatheter Edge-to-Edge Repair
TV	Tricuspid Valve
RV	Right Ventricle
RA	Right Atrium
ATL	Anterior Tricuspid Leaflet
PTL	Posterior Tricuspid Leaflet
STL	Septal Tricuspid Leaflet
ME	Mid Esophageal
DE	Deep Esophageal
SAX	Short-Axis
CGS	Coaptation Gap Size

Introduction

Intraprocedural transesophageal echocardiography guidance plays an essential role in TEER of TV. However, adequate imaging can be demanding for several reasons. First, visualization of the TV is potentially restricted due to its unfavorable anterior position that is prone to shadowing artefacts by structures closer to the TEE probe. Second, TV morphology itself is highly variable and sometimes difficult to recognize as is the identification of different pathomechanisms causing tricuspid regurgitation (TR). Finally, for a successful intervention leaflet and device interaction needs to be precisely visualized and very closely evaluated.

So far, several different imaging concepts are in use[1–7]. However, an imaging protocol that fully addresses the morphological complexity of the TV is still missing. As a tertiary referral center with a high annual caseload close to 100 transcatheter tricuspid valve interventions, we developed a guiding protocol that has constantly been further adapted over the last years. Key part of our protocol is the use of transgastric acoustic windows. They deliver a maximum of morphological and functional information for all relevant intraprocedural steps, i.e., evaluation of morphology, development of a repair strategy and visualization of leaflet/device interaction. Furthermore, the frequent shadowing artefacts experienced in transesophageal imaging are avoided using the transgastric windows. As this has not been proposed in a similar fashion, we refer to our concept as the “Mainz-Approach”. This core idea of a rigorous focus on morphology is woven into a structured protocol involving the following steps: an optimal TEE set-up in the cath-lab (1), a comprehensive verification of acoustic windows (2), a careful evaluation of TV morphology (3), development of an adequate interventional strategy (4), procedural guidance (5) and evaluation of interventional success (6). Our protocol applies to both CE-marked TEER devices in use, the TriClip system (Abbott, Chicago, IL, USA) [8, 9]and the PASCAL repair system (Edwards Lifesciences, Irvine, CA, USA) [10–12].

The Mainz-Approach

Step 1- Set-up in the cath-lab

A safe and proper set-up for the echocardiographer in the cath-lab needs to maximally reduce radiation exposure and to provide an ergonomic working environment. We highly recommend the echocardiographer's position to be at the head of the table with the C-arm in a left-lateral position to best accomplish these requirements. Only now two mobile leaded acrylic shields can be placed directly in between C-arm and echocardiographer and enough space is provided for ultrasound system, seating and a table for probe suspension (Fig. 1).

Step 2- Verification of acoustic windows and their respective views

As imaging of the TV can be restricted by its unfavorable anterior position, verification of all relevant acoustic windows is paramount. The Mainz Approach relies on two transesophageal (i.e a mid- and a deep-esophageal) and one transgastric window. Each acoustic window is used for specific views/cutting planes.

Mid-esophageal RV inflow-outflow view

Goal of transesophageal imaging is to generate unrestricted inflow-outflow views of the right ventricle (RV) that can be used as the primary cutting plane for biplane imaging and 3D rendering. Firstly, we identify the midesophageal (ME) acoustic window from which a correct inflow-outflow view of the RV can be achieved (search angle of TEE transducer typically is 60-80 degrees; Fig. 2A & B). It cuts the TV parallel to the line of coaptation of anterior and posterior leaflets with the septal leaflet. If the cutting plane is correct the perpendicular plane (generated by activation of biplane imaging) shows a mirrored 4-chamber view of the TV. As a marker of imaging quality, the septal leaflet should be fully visualized without shadowing artefact also at the anterior commissure.

Deep-esophageal RV inflow-outflow view

Often an unrestricted inflow-outflow view of the TV can be more successfully obtained from a deep-esophageal window (Fig. 2D & E). It is acquired by advancing the TEE probe into the distal esophagus directly behind the posterior wall of the right atrium (Fig. 2F). From this transducer position an unobstructed visualization of the TV is more likely as left atrium, aortic valve and interatrial septum are bypassed and shadowing artefacts are avoided. If present, it is the ideal window for performing a biplane evaluation of TV function and for acquiring high frame rate 3D volumes of the TV[1, 13, 14]. The correct search angle of TEE transducer is typically slightly higher than for the inflow-outflow view from the ME window (80-100 degrees).

Transgastric short-axis view (en face view of TV)

An essential view for TV leaflet evaluation is the transgastric short axis (SAX) or en face view generated from a transgastric window (Fig. 2G & H). It is the only 2-dimensional view providing visualization of all leaflets at the same time [1]. The aim is to generate a transversal cutting plane of the TV, showing all leaflets in one plane. Optimal orientation can be controlled by simultaneous biplane imaging showing the

TV annulus in a strict vertical orientation and the leaflet tips on the cutting plane (Fig. 2H). The TEE probe is advanced into the stomach and anteflexed with an additional turning of the probe toward the patient's right (clockwise) (Fig. 2I). Search angle rotation usually ranges between 20-60 degree, higher angles may be required in cases with very severe RV enlargement and cardiac axis deviation. Adjustments to the depth of the probe, ante-, retro-, and right-/left-flexion of the TEE probe optimize the view. If orientation is not exactly vertical, the primary plane cannot ensure the correct transversal cutting plane[(15)]. Examples of views from all 3 different acoustic windows are given in Fig. 2. It also displays the corresponding TEE probe positions that can be easily controlled by fluoroscopy throughout the procedure.

Step 3 - Evaluation of TV morphology

The TV is the most complex and anatomically variable valve of the heart. Despite its name, the TV is truly tricuspid in only about half of the investigated subjects. In the other half, it is frequently quadricuspid with an additional leaflet, most commonly presenting as a second posterior leaflet. [(16, 17)] (Fig. 3A-F).

Hence, a thorough assessment of TV morphology and the identification of the underlying pathology causing TR is key to develop a suitable interventional strategy [(18)].

Pulling the free mural wall (anterior and/or posterior leaflet) towards the septal leaflet (STL) is the principle of TEER as the STL works as an anchor leaflet for any of the devices. Thus, a sufficient STL leaflet length and mobility is crucial to guarantee successful TEER and it should be carefully evaluated before the procedure. STL radial length at the target zone, and presence of tethering are paramount to recognize, as they directly influence treatment success [(19, 20)]. Further, indentations of the septal leaflet, typically seen in the anterior part, need to be well appreciated to prevent insufficient grasping.

Especially the transgastric short axis view of TV offers a comprehensive assessment of TV leaflets, scallops, indentations, commissures and coaptation deficits (Fig. 3).

Coaptation gap size

A key anatomical feature present in the great majority of patients with progressive secondary TR [(21)]and that will limit the success of edge-to-edge repair is the coaptation gap size (CGS). It is the maximal gap size in the center of the valve. Annular dilation or spherical remodeling of the RV causing leaflet tethering both can lead to the generation of a coaptation gap, most typically between the anterior (ATL) and/or posterior (PTL) tricuspid leaflet and the STL. Irrespective of tethering pattern or annular dimensions, the CGS defines the limits of TEER therapy. Data suggests a CGS of > 7 mm as a predictor for technical failure in patients treated with 2nd generation MitraClip [(2, 19, 22)] With the newer generation devices incorporating longer device arms, TV with greater gaps (≤10mm) can still be reasonably treated with TEER. Large coaptation gaps, especially in a non-central or non-anteroseptal position have shown to yield the worst post-procedural outcomes[(19)], while treatment of isolated septal-anterior coaptation defects has shown much more favorable results [(23)] . Gap size at the target zone of device implantation needs to be differentiated from a maximal gap size in the center of the valve (as reported in the above-mentioned studies). While a gap size at the target zone defines the probability to successfully implant a device, a central gap size (as mentioned above) is associated with the probability of device success (i.e. TR reduction to ≤2+).

While the RV inflow-outflow view using biplane imaging gives an idea of the gap size, the only ways to truly appreciate and correctly measure the extend of the coaptation gap are the correctly aligned biplane transgastric short axis view (Fig. 4) and use of 3D multiplanar reconstruction.

Step 4- Device strategy

Interventional strategy in general is similar to that of TEER in the mitral valve. Device implantation is aimed at the site of the CGS (or peak of color doppler information). Due to a large gap size, this site often cannot be addressed directly, but a multiple device strategy is needed. Here, the first device(s) enable(s) addressing the CGS. Typically, a target zone offering a smaller gap size for the first enabling device(s) is found further to the commissures. In most cases, this will be anterior[8].When pursuing the clover strategy[24–26], starting anteriorly is also strongly advised as placement of posterior device(s) first leads to strong shadowing artifacts in the transgastric view, possibly even prohibiting additional clip placement further anterior.

Step 5- Procedural guidance

Procedural guidance steps include imaging of device steering, visualization of leaflet device interaction and evaluation of interventional success. Different from other suggested guiding protocols we use the transgastric SAX view as the main imaging plane to visualize device introduction into the RV and, more importantly, engagement of the device to the leaflets. Firstly, the amount of morphological information of the TV is much higher than from transesophageal views which facilitates recognition of commissures or indentations in between leaflets/scallops that need to be avoided when grasping. Secondly, the device itself, and especially the leaflet engagement and insertion of the leaflets into the device can be imaged more precisely in the transgastric view. This is due to the plethora of information provided by a transversal cutting plane but also due to less shadowing artefacts usually found in transesophageal views. The latter sometimes even disqualify transesophageal views to an extend that they cannot be used for guiding the grasping process at all. In these cases, a familiar use of transgastric views will decide over treatment success vs procedural abortion.

After correct device orientation and positioning has been achieved at the target zone, engagement of the leaflets needs to be visualized. Explicit care needs to be taken to image the bright (echo-rich) edge of the corresponding leaflets. Only then immobilization of the leaflets, when caught by the device arms, can be immediately appreciated. Also, different from transesophageal views transgastric imaging now eases visualization of how far the captured leaflet edges reach into the center of the device as the course of the complete leaflet edges can be followed (Fig. 5A). This information – essential before the device is closed – can be backed-up by biplane transgastric imaging through a “sweep” across both arms to visualize the engagement of the leaflet on the device arm (Fig. 5B & C).

In general, the imaging sector should be narrowed in order to optimize spatial and temporal resolution. This is especially relevant when the grippers/clasps are lowered, and device arms are closed – a procedural step that requires full attention and should be comprehensively recorded by a long loop. This will allow for retrospective review of leaflet grasping and give confidence in final evaluation of leaflet insertion (Fig. 5D).

An additional advantage of grasping in the transgastric view is the opportunity to immediately visualize the double (bicuspidalization technique) or triple orifice (clover technique) created by leaflet approximation, which is a crucial imaging information to ensure a successful grasping (Fig. 5E & F, Fig. 8)[24].

Step 6- TEER of TV success evaluation

Before device deployment, adequate leaflet grasping needs to be confirmed to prevent single leaflet detachment (*SLD*) (Fig. 7 & 8) or device embolization. We highly recommended to do this firstly in the SAX view of TV as this is from where grasping was visualized and leaflet insertion can be very exactly detected (Fig. 5D, Fig. 8).

Additionally, we visualize the tissue bridge using biplane imaging from a transesophageal window. Depending on the position and rotation of the device the search angle of the primary plane needs to be adjusted. This is done analogously to biplane visualization of TEER result in the mitral space (Fig. 6). If adequate insertion of both leaflets can also be ensured in this view, the device is deployed. Sometimes the difficult imaging conditions of transesophageal windows lead to undecisive information about leaflet insertion. In these cases, we highly recommend to base the decision on whether a device should be deployed on the information gained by transgastric imaging.

Assuring adequate leaflet insertion before device deployment is paramount as uneven or insufficient grasping may lead to SLD. An example on how sensitive transgastric imaging is to detect insufficient leaflet grasping is presented in Fig. 8. In a case with an early ATL detachment review of the transgastric visualization of the grasping process revealed an ATL slip leading to a suboptimal grasping length that after deployment translated into an early leaflet disconnection (Fig. 7). Obviously transgastric imaging also has a learning curve but the amount and detail of information derived makes it a powerful tool to deliver high quality TEER of the TV.

In addition, color flow Doppler (CFD) assessment before deployment is performed to evaluate adequate reduction of TR which is also a sign of adequate leaflet grasping. TV gradient has to be checked before device release especially when placing multiple devices to ensure an acceptable transvalvular gradient excluding relevant stenosis. After deployment CFD and transvalvular gradients are key to evaluate the acute effect of TEER on TR and influence the decision to implant a second or third device(27).

Conclusion

Imaging requirements in TEER of the TV are high compared to other interventional procedures and play a major role for the safety and effectiveness of the procedure. A standardized approach of periprocedural guiding is of critical importance to assure optimal results.

We recommend a systematic approach that highly relies on transgastric imaging. Only with the plentitude of morphological information gained by scanning from transgastric windows all relevant procedural steps can adequately be guided. As long as TEE is the main imaging modality to guide TEER for the TV an experienced use of the transgastric windows will have a great impact on success rates and should be a dedicated part of the imaging protocol in practice.

Disclosures

F. Kreidel and T. F. Ruf report having received travel grants and lecture and proctoring honoraria from Abbott Cardiovascular and Edwards Lifesciences. R.S. von Bardeleben reports having received advisory board honoraria from Abbott Cardiovascular, Edwards Lifesciences, Boston Scientific and Medtronic and trial steering committee and lecture honoraria from Abbott Cardiovascular and Edwards Lifesciences. All other authors have no conflicts of interest to declare.

Author contributions

Jaqueline G. da Rocha e Silva**:** Concept/design, Drafting article

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Thomas Munzel: Critical revision of article

Stephan von Bardeleben: Critical revision of article, Approval of article

Felix Kreidel: Concept/design, Critical revision of article, Approval of article

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Figure legends

Fig. 1. Set-up in hybrid OR with the echocardiographer's position at the head of the cath-lab table. Two mobile protective shields (yellow arrows) with transparent leaded screen guarantee for sufficient radiation protection. Note the C-arm position lateral to the table providing enough space for echo machine, table and seating.

Fig. 2. Essential acoustic windows for edge-to-edge repair with simultaneous biplane views and corresponding fluoroscopic images of TEE probe position; (A-C): mid-esophageal RV inflow-outflow view; (D-F): deep-esophageal RV inflow-outflow view; (G-I): transgastric short-axis view of TV.

Fig. 3. Transgastric SAX views of TV showing anatomical variability of tricuspid valve leaflets (A-C) with PTL in red, STL in yellow and ATL in blue (D-F). Depending on depth and size a smaller septal leaflet indentation (D) can be differentiated from a more pronounced septal leaflet commissure separating two septal leaflets (E; white arrows). Finally, F shows a ‘‘true view’’ rendered 3D zoom volume that gives a meaningful overview of TV morphology including the size of central coaptation gap.

Fig. 4. 3D-TEE of TV showing a large central coaptation gap (A). Schematic view of TV in the same orientation of transgastric SAX view, depicting gap size measurements of maximal gap diameter in s/l dimension (CGS, red arrow) and at two different target zones: one between anterior and septal leaflet (blue arrow) and one between posterior and septal leaflet (yellow arrow) (B). Biplane SAX view of TV with the beforementioned gap measurements (C). Biplane commissural view with

antero-posterior and septal-lateral annulus diameters (D); septal leaflet length measured at the target zone (E).

Fig. 5. A shows a TEER device still opened with both leaflets already resting on its arms (white arrows - note bright edge of leaflets). B and C document a “sweep” across the device confirming engagement of ATL on anterior device arm (yellow arrows) and of the STL on septal device arm (red arrows). D: tissue bridge of ATL and STL just after device closure (note how bright leaflet edges run directly to center of the device). E shows a typical double orifice (asterisks) after implantation of one device in anteroseptal commissure, whereas the TV in F has a triple orifice (asterisks) after implantation of one device in the anteroseptal and one device in the posteroseptal commissure.

Fig. 6. As in TEER for the mitral valve, biplane imaging to control for leaflet insertion in the TV space also relies on a correct search angle of the primary cutting plane (perpendicular to opening angle of device). As depicted in the picture, the correct search angle for the primary plane will increase from an anteroseptal to a posteroseptal device position just as is does in the mitral space with more lateral position.

Fig. 7. Serial biplane images showing a device deployment complicated by an early disconnection of the ATL with the device. Device before (A), during (B) and just deployment (C). Initially both leaflets seem to insert correctly (C) where as only a few minutes later loss of ATL insertion was noted (D). SAX view of TV with biplane

imaging showing device an intact appearing tissue bridge before deployment (E) and the detached ATL after deployment (F).

Fig.8. Successful leaflet capture (ATL and STL) by the device (A); ATL partially slips off the anterior device arm (arrow) during device closure (B); partial leaflet grasp (C), note leaflet edge not running into very center of device.

Supplementary Material (videos)

11. TEE short-axis transgastric view showing grasping sequence with correct engagement of the leaflets on device arms, device closure and immediate double orifice appreciation after anteroseptal device placement (bicuspidalization technique).
12. TEE biplane transgastric short-axis view of TV with color flow doppler showing central regurgitation and pacemaker lead at posteroseptal comissure.
13. TEE biplane transgastric short-axis view of TV with color flow Doppler showing a good result after placement of one device posteroseptal. Minimal residual regurgitation around pacemaker lead.