



Step-by-step transesophageal echocardiographic guidance for transjugular transcatheter tricuspid valve replacement with a radial force-independent bioprosthesis

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Abstract: The prohibitive risk of isolated tricuspid valve (TV) surgery encouraged rapid development of a transcatheter solution for tricuspid regurgitation (TR). The favorable results of these devices informed recent guidelines to recommend considering transcatheter treatment of symptomatic secondary severe TR in inoperable patients. Transcatheter TV repair systems usually reduce TR through leaflet approximation and direct annuloplasty. Orthotopic transcatheter TV replacement (TTVR) devices generally rely on radial force and tricuspid leaflet engagement for implantation and stability. The LuX-Valve is a novel radial force-independent orthotopic TTVR device that is operated through the trans-atrial approach. Its radial force-independency is achieved through an interventricular septal anchor tab (septal insertion) and two leaflet graspers (leaflet engagement). Such a unique design makes the intraprocedural imaging different from that of other currently available TTVR systems. The latest generation of this device, the LuX-Valve Plus, comes with a newly designed delivery system through the transjugular approach, which makes the intraprocedural monitoring and adjustment of the device even more complex for successful implantation. However, its unique imaging needs for intra-procedural guidance and post-operative evaluation have not been described before. Therefore, we aimed to elaborate the key steps of transesophageal echocardiography (TEE) to guide this novel procedure. Herein, the primary 2-dimensional (2D) and 3-dimensional (3D) echocardiographic work planes are proposed and the critical steps are emphasized for better communication between imagers and interventionists. The suitability of 2D and 3D echocardiography to guide this procedure is also discussed to increase the flexibility of choice during the implantation.

Keywords: Tricuspid regurgitation (TR); transcatheter tricuspid valve intervention (transcatheter TV intervention); transesophageal echocardiography (TEE)

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Transcatheter solutions for tricuspid regurgitation (TR)

The tricuspid valve (TV) was historically referred to as the forgotten valve and TR was usually left untreated until recent research unveiled its detrimental impact on prognosis (1). The prohibitive risk of isolated TV surgery encouraged rapid development of a transcatheter solution for TR (2), which demonstrated favorable outcomes (3,4). In recognition of this, recent updates in guidelines recommend considering transcatheter treatment of symptomatic secondary severe TR in inoperable patients (5,6).

Currently available transcatheter solutions for TR can be categorized into repair and replacement devices. To date, three of the transcatheter TV repair (TTVR) systems have been approved for commercial use, aiming at leaflet approximation [TriClip (Abbott Laboratories, Chicago, IL, USA) and PASCAL (Edward Lifesciences, Irvine, CA, USA)] and direct annuloplasty (Cardioband; Edward Lifesciences), respectively (7). For replacement devices, in addition to heterotopic valves aiming to relieve venous congestion (TricValve; OrbusNeich, Shatin, Hong Kong), several orthotopic replacement systems are under clinical and preclinical investigation. Among them, 4 of the devices [NaviGate (NaviGate Cardiac Structures, Lake Forest, CA, USA), EVOQUE (Edwards Lifesciences), LuX-Valve (Jenscare Biotechnology, Ningbo, China), and Lux-Valve Plus (Jenscare)] have published first-in-human results (8-11). These devices rely on either radial force (NaviGate, EVOQUE), tricuspid leaflet engagement (all four devices), or septal insertion (LuX-Valve and Lux-Valve Plus) for implantation and stability. The device characteristics and mechanisms of deployment are summarized in *Table 1*.

The transjugular delivery and implantation of the Lux-Valve Plus system requires intensive echocardiographic guidance and monitoring. Its unique radial force-independent design also makes the intraprocedural imaging different from other currently available TTVR systems (*Figure 1*). However, the imaging needs in the intraoperative guidance and immediate postoperative evaluation of this device have yet to be described.

This practice review thus aims to elaborate how 2D and 3D transesophageal echocardiography (TEE) are used to guide the implantation of the Lux-Valve Plus system and discusses the imaging requirements of this novel procedure.

Guiding the super stiff guidewire and the delivery system into the right ventricle (RV)

From the 3D mid-esophageal (ME) bicaval view, the superior vena cava (SVC) and the tricuspid orifice are displayed. Clockwise or counterclockwise rotation of the probe will allow visualization of the tricuspid orifice in a 3D en face view. The super stiff guidewire is first guided into the RV (*Figure 2*), and then the delivery system is inserted along the super stiff guidewire into the RV (*Figure 3*). During this process, the end of the delivery catheter should always be clearly displayed to avoid damage to the surrounding tissue and the super stiff guidewire is withdrawn after ensuring that the delivery catheter is at a suitable depth into the RV.

Adjusting the delivery system to align coaxially or parallel to the central axis of the tricuspid annulus plane

From the ME 4-chamber (4C) view, the X-plane mode and the 3D mode were activated to guide the delivery system coaxially with the central axis of the tricuspid annulus (*Figure 4*). During the adjustment, the end of the delivery system should be clearly imaged to avoid contact with surrounding structures or wrapping around the chordae tendineae, which could lead to ventricular wall perforation or tendon rupture.

Coaxiality is a common requirement for transcatheter valve implantation to avoid paravalvular leak and dislodgement (12). This is usually confirmed using two longitudinal orthogonal planes across the annular plane, which can be easily achieved for the mitral valve through the X-plane mode with the commissural view as the primary view (13). For the TV, if the abovementioned planes are insufficient to confirm coaxiality, multi-planar reconstruction can also be used (*Figures S1,S2*).

Confirming the two graspers are holding and clamping the anterior TV leaflet from the right ventricular side (critical step)

From the ME aortic valve (AV) short axis (SAX) view, slight ante- or retro-flex and clockwise or counter-clockwise rotation of the probe until the 2 rabbit-ear-like graspers of the Lux-Valve Plus can be visualized. The sample line is then placed on the graspers, and the X-plane mode is activated to monitor the opening of the graspers. It is important to confirm that the leaflet lies to the atrial side

Table 1 Summary of the characteristics of transcatheter tricuspid valve replacement devices

Characteristics	NaviGate	EVOQUE	LuX-Valve	LuX-Valve Plus
Size, mm	36, 40, 44, 48, 52	44, 48, 52	50, 60, 70 (annular)	50, 60, 70 (annular)
Anchoring mechanism	Atrial winglets and ventricular graspers	Intra-annular sealing skirt and leaflet graspers	Anterior leaflet graspers and septal anchor	Anterior leaflet graspers and septal anchor
Radial force	Dependent	Dependent	Independent	Independent
Access	Atrial (jugular approach abandoned)	Femoral	Atrial	Jugular
Delivery system size, Fr	42	28	32	32

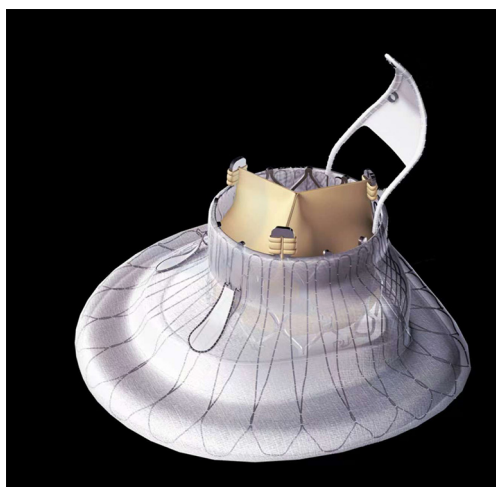


Figure 1 The Lux-Valve Plus prosthesis. The radial-force independent feature relies on the bird tongue-shaped interventricular septal anchoring component and two expanded polytetrafluoroethylene-covered graspers. Reproduction of this image is authorized by Jenscare Scientific Co., Ltd.

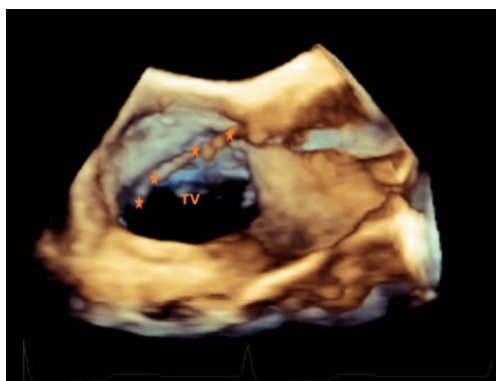


Figure 2 3D mid-esophageal bicaval view showing the super stiff guidewire (shown in orange ★) from the superior vena cava to the right ventricle. TV, tricuspid valve; 3D, 3-dimensional.



Figure 3 3D mid-esophageal bicaval view showing the delivery catheter (shown in orange ◆) advancing into the RV along the super stiff guidewire (shown in orange ★). TV, tricuspid valve; 3D, 3-dimensional; RV, right ventricle.

of both graspers. This could be judged from the limited motion of the anterior leaflet (*Figure 5*). Leaflet engagement should be carefully assessed as it is one of the major mechanisms of anchoring (9). This is especially important for the LuX-Valve system as it only has two graspers as opposed to the nine graspers on the EVOQUE valve or 12 tines on the NaviGate valve (14). In addition, 2D imaging is preferred over 3D to confirm leaflet engagement due to its better spatial resolution. Of note, the anterior leaflet is not securely clutched at this step as it requires the valve stent to expand on the atrial side of the leaflet after unsheathing to finish the clamp.

Opening of the valve disc under 3D en face view of the tricuspid orifice

After the anterior TV leaflet is grasped, the atrial valve disc

is opened and adjusted under the monitoring of a 3D en face view of the tricuspid orifice, which is obtained from the 2D ME bicaval view. The orientation of the disc is slightly tilted so that the valve stent fits the tricuspid annulus, particularly the septal portion of the annulus (Figure 6). The prosthetic valve would have been functioning at this time and the paravalvular leak can be assessed in multiple views using 2D color Doppler flow imaging (CFI) (Figure 7). It should be noted that major reposition of

the valve is not possible after the expansion of the valve stent and the opening of the atrial flange because the self-expandable valve stent would approximate the leaflet graspers and clutch the leaflets within after release. This is similar to the EVOQUE system, where the anchor tips become positioned subannular to capture the leaflets as the valve is exposed and expands (15). Slight ante-, retro-, left-, or right-flex of the delivery catheter may allow better contact of the atrial flange with the underlying tissue and consequently better seal.

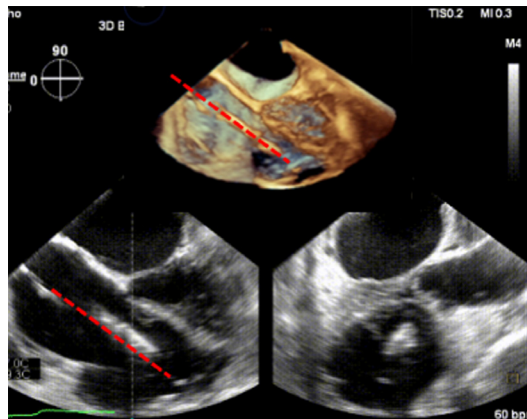


Figure 4 Mid-esophageal 4-chamber view with the X-plane mode and the three-dimensional mode activated. The delivery system aligns parallel to the central axis of the tricuspid annulus (red dashed lines).

ME 4C X-plane view to guide and monitor the deployment of the interventricular septal anchor (critical step)

Using the ME 4C view, the interventricular septal anchor piece is adjusted to be parallel to the posterior segment of the interventricular septum (IVS). The orthogonal plane of the X-plane mode is used to ensure that the anchor piece clings to the septum and to monitor the insertion of the tip of the anchor piece (Figures 8-10). If the anchors are shown to be parallel to the IVS and not in contact with the posterior septum in the non-standard ME 4C view but contacting the posterior septum in the orthogonal right ventricular SAX view, it is then necessary to retroflex the probe to obtain the standard ME 4C and right ventricular SAX views (Figures S3,S4). If the standard ME 4C

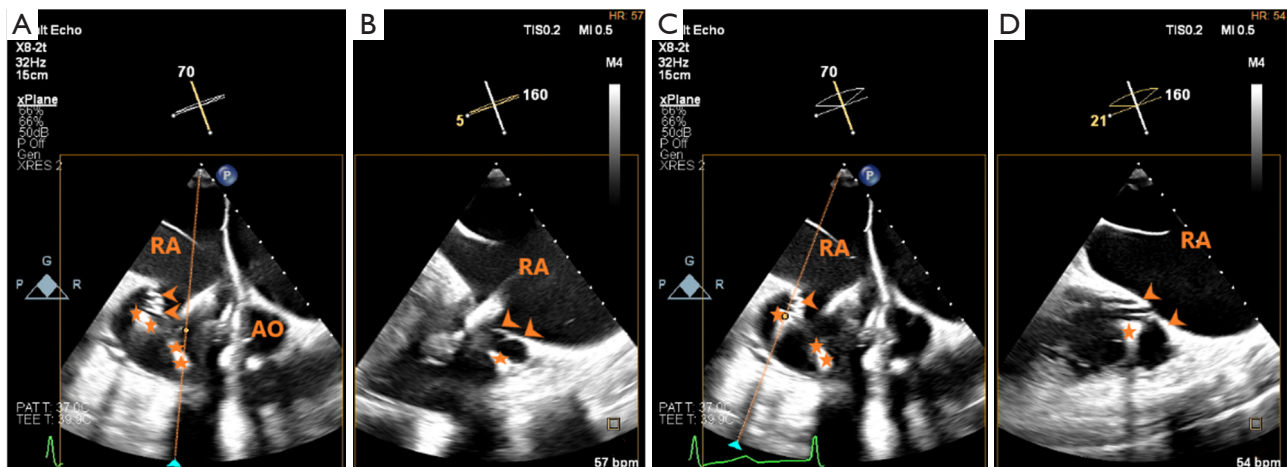


Figure 5 Left panel: ME AV SAX view (A) with X-Plane mode activated. The sample line is placed on the anterior grasper. The resulting orthogonal view (B) represents a ME RV inflow tract view, showing that the grasper is located below the TV; right panel: ME AV SAX view (C) with X-Plane mode activated. The sample line is placed on the lateral grasper. The resulting orthogonal view (D) mimics a ME RV inflow tract view, showing that the grasper is located below the TV (as shown by orange arrows). AO, aorta, RA, right atrium, ME, mid-esophageal, AV, aortic valve, SAX, shortaxis, TV, tricuspid valve.

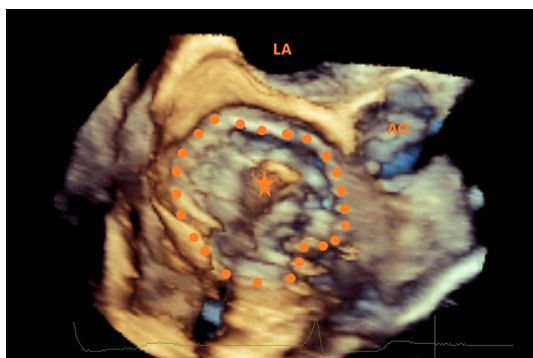


Figure 6 3D en face view of the TV, showing the fully open atrial valve disc adhering to the right atrial wall (orange dashed line). The delivery catheter (shown in orange ★) is not dissociated. LA, left atrium; AO, aorta; 3D, 3-dimensional; TV, tricuspid valve.

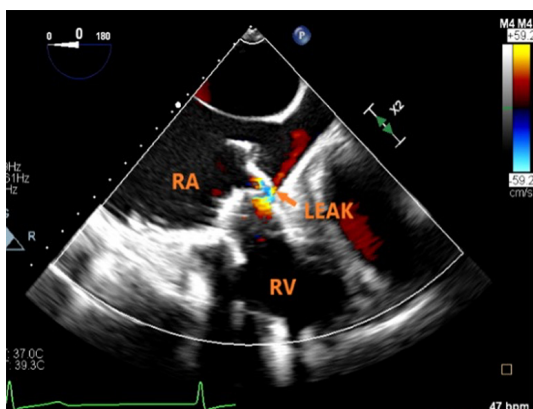


Figure 7 Mid-esophageal 4-chamber view, color flow imaging showing a mild paravalvular leak adjacent to coronary sinus (indicated by the orange arrow). LEAK, paravalvular leak; RA, right atrium; RV, right ventricle.

X-plane views demonstrate a nonparallel septal anchor, the delivery catheter can only be slightly rotated clockwise or counterclockwise until it is parallel to and opposing the septum to prevent leaflet tear.

Evaluation of the prosthetic valve function

From a 3D en face view of TV, the coaxiality of the prosthetic valve and the morphology of the valve disc could be assessed. The 2D and 3D CFI from this view could be used to assess the presence and location of paravalvular leak. Paravalvular TR quantification is preferably performed through direct planimetry of the

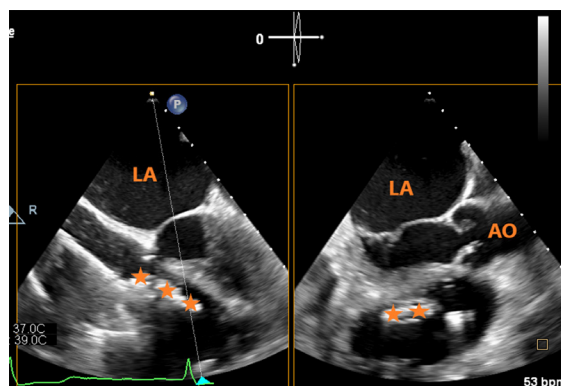


Figure 8 Mid-esophageal 4-chamber X-Plane view. Left: the anchor piece aligns parallel to the septum but not clings to it (shown in orange ★); right: the anchor does not cling to the septum (shown in orange ★). LA, left atrium; AO, aorta.

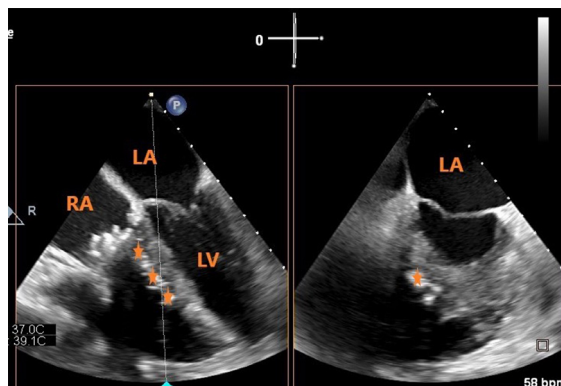


Figure 9 Mid-esophageal 4-chamber X-Plane view. Left: the anchor aligns parallel to and clings to the septum (shown by orange arrows); right: the anchor clings to the septum (shown by orange ★). LA, left atrium; RA, right atrium; LV, left ventricle.

vena contracta area under 3D CFI (16), as the regurgitant orifice is irregular and the hemispheric assumption of the proximal isovelocity surface area method is violated. Severity of the paravalvular leak can be graded as per guideline recommendation (17). Angiography can further confirm the presence and severity of paravalvular leak. Rotating the 3D en face view of TV to the ventricular side of the tricuspid orifice allows visualization of the 2 graspers and the septal anchor (Figure 11).

The maximal and mean transvalvular pressure gradient should also be assessed, though elevated pressure gradient is rare (18). If the prosthetic valve is coaxial, the paravalvular leak is moderate or less, the mean transvalvular pressure

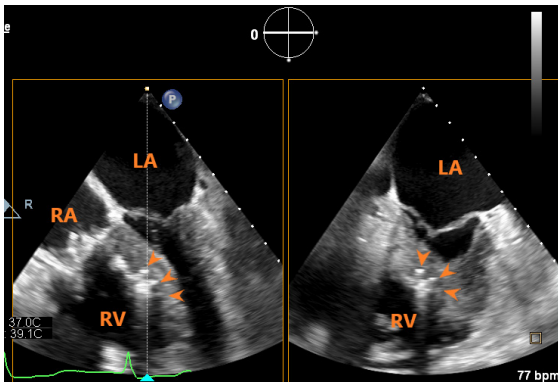


Figure 10 Mid-esophageal 4-chamber X-Plane view. Left and right: the claws on the anchor tip inserted into the septum (shown by orange arrows). LA, left atrium; RA, right atrium; RV, right ventricle.

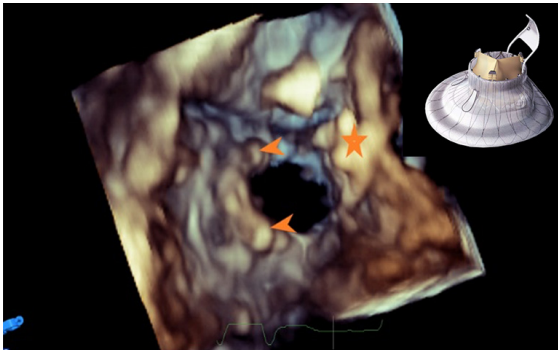


Figure 11 3D view of the right ventricle of the tricuspid valve, clearly showing the two ‘rabbit ear’ clamping keys (shown by the orange arrows) and the septal anchor piece (shown by the orange ★). A figure of the Lux-valve Plus prosthesis is placed at the upper-right corner to demonstrate the resemblance. Reproduction of the image is authorized by Jenscare Scientific Co., Ltd. 3D, 3-dimensional.

gradient is less than 2 mmHg, and no other complications such as pericardial effusion are found, the valve and delivery system can be dissociated and the delivery system can be withdrawn.

Discussion

Advantages and disadvantages of 2D and 3D echocardiography

The major steps and views of Lux-Valve Plus implantation are summarized in *Table 2*. During each step of the LuX-Valve Plus implantation, different imaging needs entail

different imaging modalities. For steps that involve definition of the general position of the device, such as confirming the coaxiality or introducing the delivery system, both 2D and 3D echocardiography can be used. However, when finer monitoring of anatomical structures or device details is needed, such as confirming that the leaflet lies to the atrial side of the two graspers or the insertion of the tip of the anchor piece into the IVS, 2D echocardiography is preferred due to its better spatial and temporal resolution. For steps requiring real-time imaging of the entire device, such as the opening of the valve disc, 3D echocardiography is the better choice. 3D echocardiography should also be used when definition of specific leaflet is hard to achieve under 2D echocardiography (19).

Future technical improvements

Current 3D technology has been shown to be able to deliver accurate chamber quantification from the deconstructed 2D views (20). Future improvement in spatial and temporal resolution of 3D echocardiography may allow accurate surveillance of much finer anatomical and device details that could significantly reduce the views needed for intraoperative guidance.

All current transcatheter TV replacement systems with published human results are not repositionable. Next-generation devices with recapturable design including the Trisol and the Intrepid system (NCT04433065) may improve the possibility of successful implantation (18).

Limitations

Several limitations of the current study should be addressed. Firstly, the transgastric projections are very useful views to illustrate the TV but are not used during the guidance. Such imaging strategy was taken to prevent accidental bleeding events. Our initial experience involves mainly end-stage patients who often may present with visceral congestion and gastric varices. The time limits in the catheterization lab may cause an anxious echocardiographer to mistakenly pull back the TEE probe without restoration into a neutral position, which could be catastrophic in such patients. The transgastric projections were thus avoided during the guidance but are only reserved for pre-procedural planning in our center. However, the authors do agree that the transgastric projections are important views for identifying the TV leaflets. In experienced centers, these views could be incorporated into the imaging protocol to help

Table 2 Summary of the echocardiographic protocols for the step-by-step guidance of Lux-Valve Plus implantation

Step	TEE views	Angle ranges	Notes
1. Guiding the super stiff guidewire and the delivery system into the right ventricle	2D and 3D ME bicaval view	70–110°	–
	3D adjusted ME bicaval view	70–110°	Slight clockwise/counter-clockwise rotation of the probe from the ME bicaval view for appropriate depth into the TA
2. Adjusting the delivery system to align coaxially or parallel to the central axis of the tricuspid annulus plane	X-plane view with ME 4C view as the primary view	~0°	The end of the delivery system should be clearly imaged to avoid contact with surrounding structures
	3D view simultaneously activated	~0°	The depth provided by 3D view helps definition of the end of the delivery system and avoid contact with surrounding structures. Further confirmation of the coaxiality can also be done
	Multi-planar reconstruction		This mode could be considered in experienced centers for better definition of the TA plane and thus better coaxiality
*3. Confirming the two graspers are holding and clamping the anterior TV leaflet from the right ventricular side	X-plane view with the adjusted ME AV SAX view as the primary view	~60°	From the ME AV SAX view, slight ante- or retro-flex and clockwise or counter-clockwise rotation of the probe until the two rabbit-ear-like graspers of the Lux-Valve Plus can be visualized
4. Opening of the valve disc under 3D en face view of the tricuspid orifice	3D en face view of the tricuspid orifice	70–110°	Slight clockwise/counter-clockwise rotation of the probe from the ME bicaval view
	Multiple views with 2D color Doppler flow		Assess paravalvular leak
*5. Guide and monitor the deployment of the interventricular septal anchor	X-plane view with ME 4C view as the primary view	~0°	Ensure the anchor piece clings to the septum
6. Evaluation of the prosthetic valve function	Multiple views required	–	Assess coaxiality, paravalvular leak and transvalvular pressure gradient

*, critical steps. 2D, 2-dimensional; 3D, 3-dimensional; ME, mid-esophageal; 4C, 4-chamber; TA, tricuspid annulus; AV, aortic valve; SAX, short axis; TV, tricuspid valve.

intra-operative decision making. Secondly, the proposed protocol is designed for teams that are beginning and/or learning how to perform the Lux-Valve Plus implantation to reduce the time needed for the proficiency of the echocardiographers and the interventionists. The simplified TEE monitoring regimen is not a substitute for the comprehensive knowledge and imaging protocols covered in current guidelines (17,21,22).

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Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://qims.amegroups.com/article/view/10.21037/qims-23-218/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all

aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was approved by institutional ethics board of Zhongshan Hospital, Fudan University and informed consent was provided by all individual participants.

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