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Review Article

Three-Dimensional Intracardiac Echocardiography for Tricuspid Transcatheter Edge-to-Edge Repair

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ABSTRACT

Patients with severe symptomatic tricuspid regurgitation face a significant dilemma in treatment options, as the yearly mortality with medical therapy and the surgical mortality for tricuspid repair or replacement are high. Transcatheter edge-to-edge repair (TEER) for the tricuspid valve is becoming a viable option in patients, although procedural success is dependent on high-quality imaging. While transesophageal echocardiography remains the standard for tricuspid TEER procedures, intracardiac echocardiography (ICE) with three-dimensional (3D) multiplanar reconstruction (MPR) has many theoretical and practical advantages. The aim of this article was to describe the in vitro wet lab–based imaging work done to facilitate the best approach to 3D MPR ICE imaging and the procedural experience gained with 3D MPR ICE in tricuspid TEER procedures with the PASCAL device.

ABBREVIATIONS

2D, two-dimensional; 3D, three-dimensional; EFS, Early Feasibility Study; FPS, frame per second; ICE, intracardiac echocardiography; MPR, multiplanar reconstruction; RA, right atrium; TEE, transesophageal echocardiography; TEER, transcatheter edge-to-edge repair; TR, tricuspid regurgitation.

The tricuspid valve has long been considered the “forgotten” valve in the surgical and medical care of individuals with severe TR.[1] Moderate-to-severe TR, however, can no longer be ignored as it affects more than 1.6 million patients in the United States and carries a yearly mortality that ranges between 15% and 45% dependent on comorbid conditions[2-5] Despite the increase in surgical volumes for the treatment of severe TR over the past 2 decades, in-hospital and surgical mortalities remain elevated at 9%-10% and only approaches 3% at specialized centers.[6-8]

Currently, advances in transcatheter repair and replacement of the tricuspid valve are emerging as more viable options for patients with excellent outcomes. Recent data have been published from transcatheter repair and replacement trials noting significant reductions in the severity

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of TR, improvements in New York Heart Association heart failure classification, improved quality of life, and a low 30-day and 1-year cardiovascular mortality of 2%-7%, thus exceeding outcomes for typical surgical therapies.[9-11]

A major factor that ensures the quality of appropriate transcatheter tricuspid procedure device placement and the associated outcomes is procedural imaging.[12] Advanced transesophageal echocardiography (TEE) with 2D and 3D multiplanar reconstruction (MPR) is a key component for transcatheter tricuspid procedures and may be most critical in TEER, as appropriate device alignment and leaflet capture are essential.[13] There are many factors in procedural imaging that may impact appropriate TEE visibility of leaflets when performing a tricuspid TEER procedure. These include shadowing from left-sided surgical aortic and mitral prostheses, tricuspid annular bands/rings, atrial septal hypertrophy, as well as anatomic thoracic features such as a horizontal heart axis, hiatal hernias, or additional thoracic/esophageal pathology. As such, it is imperative to understand and apply additional imaging techniques that can help facilitate TEER device delivery.

Intracardiac echocardiography (ICE) has the ability to overcome many of the acoustic shadowing issues as well as thoracic and esophageal pathology that can limit traditional TEE imaging. The use of 3D ICE has been used in the field of transcatheter tricuspid annuloplasty procedures and is recently becoming recognized as an adjunctive imaging strategy with 2D ICE catheters for tricuspid TEER procedures.[14-17] With improving ICE catheter technology, the application of 3D imaging with MPR-guided leaflet grasp and confirmation in tricuspid TEER procedures has added value beyond the use of more traditional 2D ICE. As application of advanced 3D ICE technologies emerges, it is essential to understand the fundamentals and advanced teamwork of this technology to drive appropriate tricuspid TEER outcomes. The aim of this paper is to describe the in vitro lab-based imaging work done to facilitate the best approach to 3D MPR ICE imaging and describe the procedural experience gained in the application of 3D MPR ICE for tricuspid TEER with the PASCAL device.

Lab-Based Work for Tricuspid Imaging

An animal beating heart model was constructed at the Edwards Lifesciences Imaging Laboratory in Irvine, California. The model consisted of a pump system to simulate pulsatile flow and "systolic and diastolic" motion of the tricuspid valve in an explanted antelope heart. A mock inferior vena cava was constructed to allow for insertion of the PASCAL Delivery system, a steerable 14F Oscor Inc (Palm Harbor, Florida) sheath for ICE catheter support and directionality, and a Siemens Healthineers ACUSON AcuNav Volume ICE Catheter (Erlangen Germany) with 2D and 3D MPR capabilities. A mock esophagus was constructed for insertion of Phillips Epiq X8 transesophageal imaging probe (Bothel, WA; Figure 1).

In the imaging laboratory, the use of the Oscor steerable sheath to house the ICE catheter was deemed essential for imaging stability and image plane optimization with minimal manipulation. The sheath was placed into the low right atrium (RA), and subsequently, the ICE imaging catheter was advanced until the imaging footplate was fully exposed from the sheath housing. The ICE catheter was rotated clockwise, and anteflexion was used to visualize the anterior and posterior leaflets of the tricuspid valve in the inflow/outflow view (Supplemental Video 1). With appropriate 2D visualization of the inflow/outflow view (Figure 2a), 3D MPR image acquisition can be initiated (Figure 2b), although frame rate and resolution notably decrease. When the 3D MPR imaging planes are launched, the primary view of anterior and posterior leaflets in the inflow/outflow view is displayed in upper left window (red plane), whereas the secondary orthogonal view of the septal to anterior or posterior-lateral is displayed in the upper right window (green plane). Thus, from left to right of the screen, the working views for tricuspid imaging can be displayed with the acronym P-A-S-L for posterior, anterior, septal, and lateral. Although there is no "lateral leaflet" of the tricuspid valve, this standardized nomenclature is established to help guide location and trajectory of the implant catheter as well as directionality of the PASCAL device paddles. The third imaging plane (blue plane) is the short axis view displayed in the left lower window with the 3D full volume rendering in the lower right window. To assess for a septal to anterior-lateral leaflet grasp, the green imaging line is shifted anteriorly and can be independently rotated counterclockwise with the "lock" feature off to align perpendicular to the leaflet coaptation plane (Supplemental Video 2). To assess for a septal to posterior-lateral leaflet grasp, the green imaging line is shifted posterior and independently rotated clockwise for perpendicular alignment (Supplemental Video 3). Supplemental Videos 4 and 5 demonstrate imaging of anterior-septal and posterior-septal PASCAL device alignment and leaflet capture, respectively, with the green imaging plane parallel to the grasping paddles and remaining perpendicular to the leaflet coaptation plane that was previously defined.

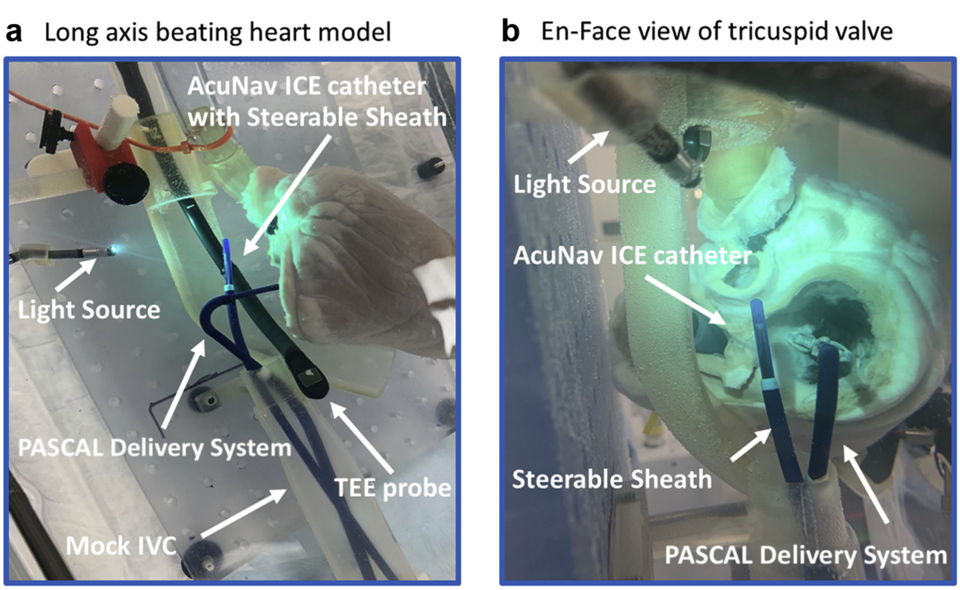

Figure 1. Animal cadaver beating heart model with PASCAL repair system, Oscor steerable sheath, Siemens ACUSON AcuNav Volume intracardiac echocardiography (ICE) catheter in long axis view (a) and en-face view (b).
Abbreviations: IVC, Inferior vena cava; TEE, transesophageal echocardiography.

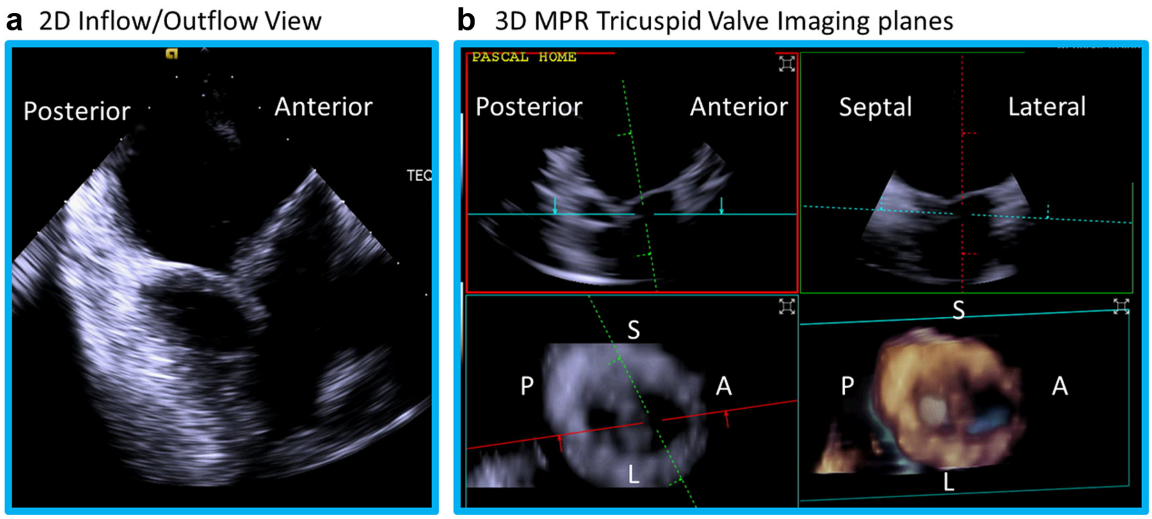

Figure 2. Still frame 2D ICE image of inflow/outflow view of tricuspid valve with anterior and posterior leaflets (a). Still frame 3D ICE imaging planes with posterior (P) and anterior (A) leaflets in the inflow/outflow view with the red plane aligned parallel to the septal leaflet. The green plane, orthogonal view, has been unlocked and counter clockwise rotated to align for a septal (S) and anterior/lateral (L) leaflet grasping view. The blue plane represents the multiplanar reconstruction rendered 3D short axis view of leaflet tips with the corresponding 3D volume (b).
Abbreviations: 2D, two-dimensional; 3D, three-dimensional; ICE, intracardiac echocardiography; MPR, multiplanar reconstruction.

The keys to 3D ICE MPR image optimization for leaflet assessment and capture begin with optimization of 2D imaging. Start with a large 2D field of view with attention to surrounding anatomic structures and ICE catheter alignment to eliminate any shadow from the PASCAL delivery system over the tricuspid valve. Further 2D imaging adjustments for leaflet analysis are made with fine clockwise or counterclockwise rotation of the ICE catheter to improve image quality with further 2D image refinement with slight flexion/extension of the steerable sheath and or advancement/retraction of the sheath and probe as one unit. Once the imager has established a clear, nonshadowed, artifact-free 2D view, further 2D optimization is facilitated by decreasing field depth and narrowing the lateral imaging plane to maximize line density before launching 3D MPR. Once in the MPR mode, improved line density and frame rates can be achieved with narrowing the orthogonal elevation plane.

The use of the steerable sheath in the laboratory testing provided improved stability of the ICE catheter during the procedure as opposed to direct ICE catheter access alone. The flexibility of the sheath tip allowed for refinement in imaging planes to evaluate the leaflets with 2D imaging and facilitated 3D MPR evaluation. The steerable sheath also helped overcome the impact of the inferior vena cava angle on the ICE catheter to prevent ICE catheter whip that can occur when the imaging catheter is "ante-flexed" while being rotated. Additional imaging challenges are encountered when the ICE catheter is directly behind the PASCAL delivery system. To avoid these shadowing artifacts advancing the steerable sheath in the neutral position to a higher perch in the RA, superior to the PASCAL delivery system, followed by slight anteflexion of the ICE imaging catheter, best facilitates an anterior-septal leaflet imaging assessment for PASCAL deployment and leaflet approximation. For imaging of posterior-septal leaflet grasping, the ICE catheter is retroflexed to a neutral position, and both the steerable and the ICE catheters are withdrawn inferiorly into the RA to the level or slightly below the trajectory of the PASCAL delivery system (Figures 3a and b). If imaging challenges

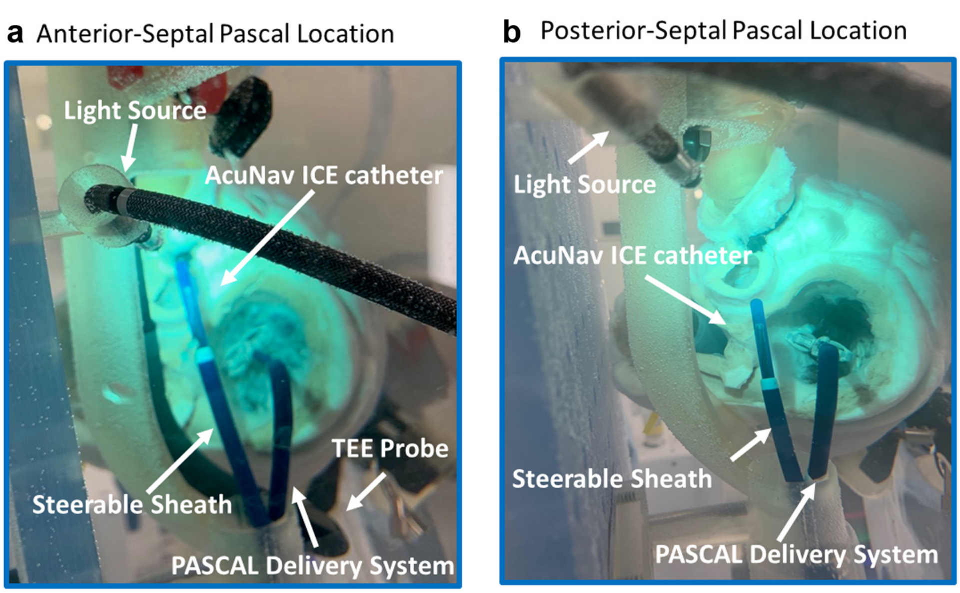

Figure 3. Siemens AcuNav intracardiac echocardiography (ICE) catheter superior in mock right atrium for imaging alignment of PASCAL implant in the anterior-septal position (a) and withdrawn inferiorly for imaging alignment of PASCAL implant in the posterior-septal position (b).
Abbreviation: TEE, transesophageal echocardiography.

with echo shadowing or artifact still persist, the sheath and ICE imaging probe should be brought back to the neutral position. Advancing both the sheath and the ICE probe slightly superior followed by anteflex of the sheath will preferentially image more posterior on the tricuspid annulus, whereas, conversely, retroflexion will image more anterior on the annulus.

2D and 3D ICE Use in Tricuspid TEER With the PASCAL Device

In the assessment of ICE imaging in tricuspid TEER with the PASCAL device as part of the CLASP TR Early Feasibility Study (EFS), 4 sites used either 2D or 3D ICE. The selection of 2D vs. 3D was based on site-specific preference and availability of imaging catheters. Overall, ICE was used in 15 cases for the evaluation of 25 PASCAL device implants. Two-dimensional only ICE was used in 10 of the 15 cases, and the remaining 5 cases used the Siemens ACUSON AcuNav Volume ICE catheter with 3D MPR. Figure 4 shows PASCAL device use and implant locations. The primary reason for ICE utilization at the sites was septal leaflet shadowing during TEE imaging due to challenging midesophageal anatomy/views and utilization of ICE to confirm leaflet capture (n = 8). In addition, 2D and 3D MPR ICE imaging were performed to overcome imaging challenges of acoustic shadowing from left heart prosthetic valves and pacemaker leads (n = 2) and to facilitate PASCAL leaflet grasping between septal chordae (n = 3).

Tricuspid TEER PASCAL EFS Case Examples

The home view for 2D and 3D ICE imaging is the inflow/outflow view as discussed earlier. From there, the image sector is narrowed, and depth is decreased to facilitate higher frame rates for 3D imaging. Care must be taken to balance sector size for imaging optimization with over narrowing and limiting anatomic features that can help facilitate spatial orientation. Three-dimensional MPR with 3D live assessment of the inflow/outflow, septal-lateral, or atrial en-face view can be viewed simultaneously with the 3D volume rendering rotated around the z-axis approximately 90° to display the aorta at approximately 5 PM on the clock face (Supplemental Video 6). When the primary image is set in the inflow/outflow view, the anterior aspect of the tricuspid annulus is to the far right of screen, and the 3D volume rendering will be initially displayed in this aspect. Clockwise rotating the 3D image to the 5 o'clock position facilitates the same orientation used with TEE-guided imaging. Color Doppler assessment can be added on in this view for assessment of the origin of TR, although the frame rate in volumes per second (VPS) decreases from 16 VPS to 9 VPS (Supplemental Video 7). While the full-screen 3D live image can be displayed (Supplemental Video 8), the working views for leaflet assessment and device alignment are obtained in the 3D MPR modality (Supplemental Video 9). In Supplemental Video 9, the red imaging plane is aligned parallel to the septal leaflet providing the inflow/outflow view, and the green plane is aligned orthogonal showing the septal and lateral grasping view. En-face assessment of the PASCAL device is seen in the blue plane, and the 3D live image is displayed with Z-rotation of the 3D image to display the aorta at 5 o'clock on the clock face. In Supplemental Video 10, the PASCAL device was advanced under the tricuspid valve and retracted with capture of the lateral leaflet. Due to the septal to lateral trajectory of the PASCAL delivery system noted in Supplemental Video 10, note that the tip of the septal leaflet was curling at the top of the PASCAL paddle and not fully seated on the device. As such, the PASCAL device trajectory was shifted to facilitate septal and lateral leaflet capture (Supplemental Video 11). Note the change in the imaging depth from Supplemental Video 10 to Supplemental Video 11 to facilitate repositioning and the corresponding decrease in frame rate from 16 VPS to 8 VPS. Imaging depth was readjusted to further inspect septal and lateral leaflet insertion into the PASCAL device, the PASCAL device was closed, and color Doppler imaging showed a significant reduction in the degree of TR from severe to mild with color Doppler frame rate at 10 VPS (Supplemental Video 12). With the release of the PASCAL device from the delivery system, repeat 3D MPR and 3D live assessment demonstrated the stability of the device across the septal and anterior-lateral leaflet with residual mild TR posterior to the implant (Supplemental Video 13).

Supplemental Videos 6-13 demonstrate the first experience with the Siemens AcuNav 3D MPR Volume ICE catheter in CLASP TR EFS. Imaging refinements based on this first experience were applied to future cases. For specific imaging and directionality of the PASCAL paddles and alignment across the septal and lateral leaflets, the short axis imaging plane (blue plane) should be adjusted to the level of the paddles, whereas the orthogonal grasping view (green plane) is adjusted in the short axis view for parallel imaging of the PASCAL paddles in the septal-lateral grasping view (Supplemental Video 14). Platforms that allow for an enlarged view of the 3D MPR imaging planes at the time of leaflet insertion (Supplemental Video 15a) and clasp lowering (Supplemental Video 15b) can be beneficial for improved assessment of true leaflet capture. This technique was found to be extremely valuable in alignment and assessment for PASCAL device deployment with a second device (Supplemental Video 16).

Strength and Limitations of 2D and 3D ICE in Tricuspid TEER Imaging

Although TEE imaging with 3D MPR is currently the gold standard for guiding tricuspid TEER therapies, ICE imaging with 2D and 3D MPR

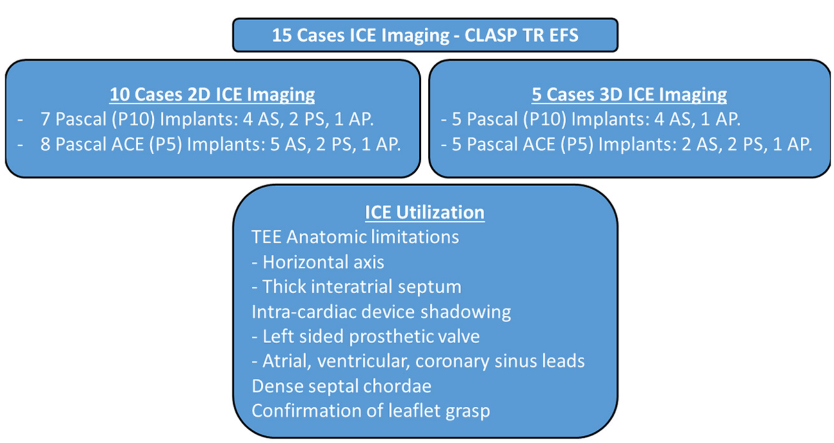

Figure 4. Flowchart of two-dimensional (2D) and three-dimensional (3D) intracardiac echocardiography (ICE) experience in CLASP II TR Early Feasibility Study (EFS).
Abbreviations: AP, anterior-posterior; AS, anterior-septal; PS, posterior-septal; TEE, transesophageal echocardiography; TR, tricuspid regurgitation.

capabilities has many theoretical as well as practical advantages over standard TEE. Two-dimensional ICE imaging improves near-field image resolution, as the imaging frequency with ICE is nearly double that for TEE at 6-8 MHz compared with 3.3-4.4 MHz. Frame rate acquisition in 2D ICE can be maximized up to 95-130 frames per second (FPS) depending on sector size, whereas the 2D TEE imaging range is typically 60-75 FPS and is obtained at a greater physical distance from the tricuspid valve and annulus. With the addition of color Doppler imaging, frame rates decrease to 29-34 FPS for both 2D ICE and TEE. As such, despite the theoretical advantage of 2D ICE frame rates, the image quality difference between TEE and ICE with or without color Doppler imaging is not markedly different. When switching from 2D TEE to 3D MPR TEE, frame rates drop to approximately 20 FPS, and 3D MPR TEE with color Doppler further drops to 15-18 FPS. In comparison, when the Siemens AcuNav ICE catheter imaging setup was appropriately optimized, 3D MPR ICE imaging can achieve frame rates nearly comparable to those of TEE. Optimized 3D MPR ICE imaging was able to achieve a frame rate of 16 VPS with a small reduction in frame rate to 10-13 VPS with the addition of color Doppler (Supplemental Videos 10-13). While the frame rate and image quality are lower in the 3D MPR modes in ICE compared with TEE (16 FPS vs. 20 VPS), direct nonshadowed leaflet visualization and CLASP deployment and confirmation can be enhanced in certain instances. Figure 5 shows the review of the strengths and limitations of 2D and 3D ICE and TEE. Three-dimensional MPR ICE imaging was determined to be essential in 3 of the 5 cases in the EFS series in which it was used. This was primarily driven by improved imaging planes for direct leaflet visualization that otherwise were shadowed during TEE imaging. Direct leaflet visualization in these circumstances was achieved via 3D MPR for direct leaflet alignment as demonstrated in Supplemental Videos 14-16. Likewise, 2D ICE was deemed essential in 7 of the 10 cases in the EFS series. While 2D ICE imaging has been proven to be successful in tricuspid TEER procedures,[16] it is limited by its "scope of view" with confirmation of device location and directionality based on the integration of fluoroscopic imaging.

Beyond the imaging acquisition and image quality issues noted, ICE imaging with the Siemens AcuNav ICE catheter housed in a steerable sheath remained stable with minimal manipulation of the sheath or catheter once the appropriate inflow/outflow home imaging position was found. Once set in the home view, sheath and ICE catheter positioning in the RA were only changed when a second or third device was placed. No vascular complications were attributed to ICE. In comparison, although TEE imaging is considered safe, overall complications rates for both minor and major events are approximately 1.5%.[18] Within the realm of TEE-guided cardiac interventions, postprocedure esophagogastroduodenoscopy discovered up to 40% of patients had either esophageal lacerations or intramural hematomas with longer procedure times and suboptimal image quality as independent predictors of these complex lesions.[19]

The limitations in the adoption of either 2D or 3D ICE imaging in tricuspid procedure are multifactorial. First, there is an additional cost to the procedure with 3D catheters, typically 5 times the price of a 2D catheter. In addition, unlike TEE-guided imaging where imaging probes are sterilized and reused multiple times, 2D and 3D ICE catheters are only approved for a single patient use. Second, costs increase with increased procedural time with the utilization of additional imaging technologies and comparison of imaging between ICE-guided and TEE-guided imaging. Finally, there is a learning curve with not just 2D but additionally 3D ICE in the assessment of the tricuspid valve and leaflets that takes a dedicated team approach. As such, initial application of 2D and 3D ICE imaging in tricuspid procedure will most likely be pursed in limited "centers-of-excellence" with the development of imaging protocols and "tips and tricks" of procedural setup before dissemination of the education and adoption of these techniques more broadly.

Future Directions

For 3D MPR and 3D real-time ICE imaging to gain a foothold in tricuspid valve procedures, further advancement of ICE catheters is

	2D ICE	2D TEE
Strengths and Limitations	▪ Highest spatial resolution: - 6-8 MHz imaging ▪ Highest temporal resolution: - 90 -130 FPS ▪ Similar temporal resolution with color Doppler imaging: 30-35 FPS ▪ Closer to valve and annular plane ▪ Limited depth of imaging: Difficult to visualize far field structure	▪ Lower spatial resolution: - 3-5 MHz imaging ▪ Lower temporal resolution: - 60-75 FPS ▪ Similar temporal resolution with color Doppler imaging: 30-35 FPS ▪ Distant from valve and annular plane ▪ Improved depth of imaging: Superior visualization of far field structures
	3D ICE	**3D TEE**
Strengths and Limitations	▪ Lowest temporal resolution: - 10-18 VPS without color Doppler - 8-14 VPS with color Doppler ▪ Ability to image leaflets not well visualized by TEE ▪ Limited MPR orthogonal field of view and 3D field view – 90^{O} x 50^{O} ▪ High cost of single use catheters ▪ Venous vascular access bleeding risk	▪ Reduced temporal resolution: - 20-30 VPS without color Doppler - 12-24 VPS with color Doppler ▪ Anatomic challenges of esophageal imaging, shadowing of septal leaflet ▪ Improved MPR orthogonal field of view and 3D field view – 90^{O} x 90^{O} ▪ Cost of TEE probe/sterilizations/service ▪ Gastrointestinal trauma risk

Figure 5. Strengths and limitations of two-dimensional (2D) and three-dimensional (3D) intracardiac echocardiography (ICE).
Abbreviations: FPS, frames per second; MPR, multiplanar reconstruction; TEE, transesophageal echocardiography; VPS, volume per second.

needed from all ultrasound manufacturers. Although there are currently 3 separate 3D ICE imaging catheters on the market, the present article focuses on the use of the Siemens AcuNav Volume imaging catheter, as it was the only available 3D ICE imaging catheter available during the CLASP II TR EFS period. The AcuNav Volume imaging ICE catheter used in this period is a phased array transducer, similar to its predecessor, the AcuNav V, and provides a 3D volume field of view increased from 90° × 24° to a 90° × 50° volume set. Although this has been a substantial improvement in the 3D volume set for short-axis 3D visualization and 3D MPR manipulation, challenges can still persist in complete imaging of the entire tricuspid annulus. Further development of an ICE catheter with 90° × 90° 3D volume field with improved line density and frame rates will be needed so that there is little distinction between TEE and ICE imaging. With a future advancement in ICE catheter imaging and further procedural experience, the possibility exists for movement toward ICE imaging for complex valve repair or replacement procedures as an enhanced imaging modality at potentially a lower risk compared with traditional 3D TEE imaging. Advancement toward ICE imaging and potentially away from TEE imaging may be raised as a concern within the imaging community. Although 2D and 3D ICE have typically been "housed" within the realm of electrophysiology and interventional cardiology, primarily due to intravascular access, 3D ICE imaging is still truly a complex imaging procedure that requires insight from "structural" echocardiographers as part of the procedural heart team. In addition, the future development of lower profile ICE catheters may also support alternative vascular access strategies for imaging from the right internal jugular vein. This advancement would shift the ICE catheter manipulation and imaging setup to the "structural" echocardiographer with room setup nearly identical to that of TEE-guided tricuspid valve procedures. Currently, when transitioning from TEE to ICE imaging, communication between the "structural" echocardiographer and interventional cardiologist/cardiac surgeon is essential to define the imaging planes, as different echo platforms and software systems have varied 3D MPR manipulation and Z-rotation capabilities. Furthermore, advanced structural echocardiographers possess in-depth knowledge of the anatomy and pathophysiology of TR, with combined knowledge of interventional device/delivery systems that is essential in the successful application, delivery, and outcomes of transcatheter tricuspid valve treatment strategies. Much like transcatheter mitral valve procedures today, engaged and dedicated "interventional structural imagers" may be able to advance the field of tricuspid ICE imaging in partnership with interventional cardiology for a potential transition to conscious sedation that would eliminate risks associated with TEE and prolonged anesthesia in tricuspid procedures. Furthermore, insights from the advancement of tricuspid imaging with ICE will carry over beyond TEER therapies to transcatheter tricuspid annuloplasty repair and tricuspid valve replacement procedures. Integrating 3D ICE imaging into tricuspid procedures will take dedication from the not just the imaging team and the heart team, it will take dedication from health systems asked initially to support the additional physical and time costs of these procedures. Future investigation will be needed to fully determine the added value that ICE imaging brings to all tricuspid procedures with improving procedural outcomes, future reduction in procedural time, and, most importantly, improving overall patient outcomes and quality of life. This teamwork-based integration of advanced echocardiographic TEE and ICE imaging in the CLASP TR EFS has been successfully demonstrated and will continue to be advanced to improve tricuspid therapies and patient outcomes.

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Supplementary Material

Supplemental data for this article can be accessed on the publisher's website.

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