Initial Experience with a Novel Real-Time Three-Dimensional Intracardiac Ultrasound System to Guide Percutaneous Cardiac Structural Interventions: A Phase 1 Feasibility Study of Volume Intracardiac Echocardiography in the Assessment of Patients with Structural Heart Disease Undergoing Percutaneous Transcatheter Therapy

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Background: Intracardiac echocardiographic (ICE) imaging is a modality increasingly used to guide percutaneous cardiac structural interventions. Until recently, ICE imaging has been limited by the presence of only two-dimensional imaging planes and requires considerable catheter manipulation to visualize certain targets. The aim of this study was to assess the feasibility of a new three-dimensional (3D) volumetric ICE system to provide imaging guidance in 15 patients undergoing percutaneous cardiac structural interventions.

Methods: The Siemens AcuNav 3D volumetric ICE catheter was used to guide interventions in 15 patients. Imaging was performed at 6 and 8 MHz without color Doppler flow mapping and at 4 and 6 MHz with color Doppler flow mapping. The images were independently reviewed, and the ability to visualize specific structures was assessed by two independent and expert ICE imagers.

Results: The majority of patients (n = 11 [73%]) were undergoing percutaneous transcatheter closure of patent foramen ovales (n = 3 [20%]) or atrial septal defects (n = 8 [53%]). Three patients (20%) underwent balloon valvuloplasty for mitral stenosis. One patient (7%) underwent a diagnostic study for congenital heart disease. There were no significant differences in image scores between 3D and two-dimensional imaging without color Doppler in clinically important targets. With color Doppler, there were decreased image scores in the 3D images. Three-dimensional images provided improved imaging of devices and catheters and of the relationship between atrial septal defect devices and the aorta.

Conclusion: Three-dimensional volumetric ICE imaging can be successfully used to guide structural heart disease procedures. It has the potential to provide greater anatomic information during interventions. Further improvement in its imaging capabilities is required to improve color Doppler mapping and volume size capabilities. (J Am Soc Echocardiogr 2014;■:■-■.)

Keywords: Intracardiac echocardiography, Structural heart disease intervention, Mitral valve disease, Atrial septal defect, Patent foramen ovale

Percutaneous transcatheter intervention for structural heart disease is relying increasingly on echocardiography to help facilitate appropriate patient selection, provide real-time procedure guidance, assess the outcomes of interventions, and assess for complications.[1] A wide variety of echocardiographic modalities are available for use in this setting, each with unique advantages and limitations.[1-3] Intracardiac echocardiographic (ICE) imaging may be used to guide some structural interventions, as it offers imaging that is similar to imaging with transesophageal echocardiography (TEE) but without the need for additional echocardiographic support and without the need for

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Abbreviations

ASD = Atrial septal defect

DICOM = Digital Imaging and Communications in Medicine

ICE = Intracardiac echocardiographic

PFO = Patent foramen ovale

TEE = Transesophageal echocardiography

3D = Three-dimensional

2D = Two-dimensional

esophageal and (in some cases) endotracheal intubation.[4-9] Until recently, ICE has been limited to only two-dimensional (2D) imaging planes and requires considerable expertise and manipulation of the catheter to visualize some imaging targets.

Real-time three-dimensional (3D) imaging has the potential to improve procedural guidance; quickly and easily locate guidewires, catheters, and devices; and provide greater anatomic information during percutaneous interventions. The introduction of this modality to TEE has been quickly adopted into complex structural interventions such as MitraClip repair.[10,11] A novel real-time 3D intracardiac ultrasound system has now been developed and received US Food and Drug Administration approval for use in humans. We evaluated the feasibility of using this imaging modality and describe the results of our experience in a series of 15 patients with structural heart disease who were undergoing percutaneous interventions.

METHODS

AcuNav V System

The 3D (volumetric) version of the Siemens AcuNav ICE catheter (Siemens Acuson, Mountain View, CA) is approved by the Food and Drug Administration for clinical use. The AcuNav V ultrasound catheter is a single-use, 10-Fr intracardiac catheter capable of volumetric reconstruction of intracardiac images with real-time 3D formatting ("3D ICE imaging"), with a volume size of 22° × 90°. The AcuNav V catheter is connected to the Accustom SC2000 ultrasound platform with a SwiftLink V connector. Both the AcuNav V catheter and the SC2000 platform with Software Revision 2.0 have received 510(k) approval.

Study Design and Image Evaluation

Our primary objectives were to assess the feasibility of using the AcuNav V 3D ICE catheter in the imaging of structural and valvular heart disease interventions and to compare the information obtained to standard 2D ICE imaging (ClinicalTrials.gov Identifier: NCT01669551).

We evaluated the imaging catheter in 15 patients with patent foramen ovales (PFO), atrial septal defects (ASD), or mitral stenosis. The study was approved by the institutional review board at the University of Pennsylvania, and all patients provided informed consent before entry. As part of our standard protocol for patients undergoing structural interventions, all patients in this study underwent 3D TEE before intervention. This was done for patient selection to ensure adequate anatomy for a percutaneous approach, for procedural planning, and for defect sizing for patients with ASDs and PFOs. The performance of preintervention 3D TEE was independent of the modality ultimately selected to guide the procedure. For patients who ultimately were referred for percutaneous intervention, 3D ICE imaging was considered for procedural guidance on the basis of the inclusion and exclusion criteria listed below. Fifteen such patients were identified. Images obtained in these patients by 3D volumetric ICE imaging were compared with those obtained in the 2D mode both before and after intervention.

Imaging was performed at 6 and 8 MHz and was performed with and without color Doppler flow mapping. Three-dimensional images were rotated and reconstructed in multiple planes in real time during the procedure using the ultrasound platform. All images were saved in Digital Imaging and Communications in Medicine (DICOM) format and transferred to a DICOM server (ProSolv Cardiovascular, Indianapolis, IN). The images were carefully reviewed and scored after the procedure on a DICOM digital workstation by two independent and expert ICE imagers (F.E.S. and H.C.H.) who have experience in interpreting >500 ICE studies. A consensus on image quality ratings was reached between investigators for each imaging target that was recorded. A semiquantitative scoring system was used to assess image quality (0 = poor image, 1 = satisfactory image, 2 = excellent image).

In addition to rating each image according to the above scale, general statements made about each case images were rated by the reviewers on a numeric scale (1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree):

1. The cardiac structures imaged in this procedure were successfully imaged with the imaging catheter.
2. It took less time to successfully image these cardiac structures as compared to 2D imaging.
3. The cardiac devices used in this procedure were successfully imaged with the imaging catheter.
4. It took less time to successfully image these cardiac devices as compared to 2D imaging.
5. The use of the imaging catheter effectively helped in guiding the manipulation or positioning of the cardiac devices.

Additional questions that were answered for each case included the following:

1. How would you rate the 3D rendering quality of the imaging catheter? (1 = very poor, 2 = poor, 3 = satisfactory, 4 = good, 5 = excellent)
2. What advantages does the real-time 3D rendering bring over traditional 2D imaging (rank by importance)? (List)
3. What disadvantages does the real-time 3D rendering bring over traditional 2D imaging (rank by importance)? (List)
4. Is the size of the acquired ultrasound volume well suited for use in this procedure? (yes/no)
5. If no, what size do you anticipate would be preferable? (List)
6. How would you rate the manipulation of the imaging catheter using the four-way steering capability overall? (1 = very poor, 2 = poor, 3 = satisfactory, 4 = good, 5 = excellent)
7. The torque of the imaging catheter is acceptable. (1 = Strongly disagree, 2 = Disagree, 3 = Neither agree nor disagree, 4 = Agree, 5 = Strongly agree)
8. Do you envision specific aspects of the procedure in which the imaging catheter could bring clinical (or other) benefits where 2D imaging does not (rank by importance)?
9. Do you envision specific aspects of the procedure in which the imaging catheter could bring clinical (or other) benefits where 2D/3DTEE does not (rank by importance)?

Eligible patients for the study were aged ≥18 years and had been referred to the catheterization laboratory for transcatheter therapy with ICE imaging for PFO, ASD, or mitral stenosis. Exclusion criteria included inability to provide informed consent, inadequate femoral venous access, class IV congestive heart failure in patients who did not require intubation for their procedures, coagulation abnormalities, presence of intracardiac thrombus or deep venous thrombosis, and inability to perform ICE imaging or planned TEE instead of ICE imaging.