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Feasibility Study of Real-Time Three-Dimensional Intracardiac Echocardiography for Guidance of Interventional Electrophysiology

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SMITH, S.W., ET AL.: Feasibility Study of Real-Time Three-Dimensional Intracardiac Echocardiography for Guidance of Interventional Electrophysiology. *The authors tested the feasibility of real-time three-dimensional intracardiac echocardiography for guidance of interventional electrophysiological studies. The three-dimensional scanner uses a matrix array ultrasound transducer of 64 channels operating at 5 MHz in a 12 Fr catheter. The system features real-time three-dimensional image rendering and produces up to 60 volumetric scans per second. Using an open-chest sheep model, real-time three-dimensional images of anatomic landmarks were obtained, including the pulmonary veins and coronary sinus, which are of value in electrophysiological procedures. In vivo radio frequency ablation procedures in the right ventricle were also monitored, which yielded lesions of high image contrast. (PACE 2002; 25:351–357)*

two-dimensional array, volumetric ultrasound imaging, intracardiac ultrasound

Intracardiac Echocardiography (ICE) has gained increasing acceptance as a useful clinical tool for applications in interventional electrophysiology. The extensive research literature in ICE has recently been reviewed in articles by Kalman et al.[1] and Bruce et al.[2] who described electrophysiological applications including direct visualization of cardiac anatomy, evaluation of the accuracy of catheter tip placement, and measurement of lesion size and location from radiofrequency (RF) ablation. ICE may also lead to clinical benefits by improving guidance during technically difficult procedures like transseptal puncture and coronary sinus access. This may have the additional advantage of reduced flouroscopic exposure to the patient and medical personnel.

Current commercial ICE systems include two technologies: (1) a mechanical system that uses a 9-MHz rotating ultrasound transducer to produce a 360-degree scan perpendicular to the long axis of a 9 Fr catheter (EP Technologies, Boston Scientific, San Jose, CA, USA) and (2) a phased-array system that uses a 64-channel linear array transducer operating at a center frequency of 8 MHz to produce a sector scan parallel to the long axis of a 10 Fr catheter (Acuson Corporation, Mountain View, CA, USA).

Notwithstanding these encouraging results, there remain challenges associated with conventional two-dimensional ICE for the guidance of interventional electrophysiology. One problem is the intrinsic limitation of a two-dimensional scanning technique as a guide for an interventional catheter that must be manipulated in three dimensions. Attempts have been made to produce three-dimensional intracardiac ultrasound images using off-line computer reconstruction to combine sequential two-dimensional images obtained during catheter pull back.[3,4] The image acquisition entailed cardiac gating combined with computer reconstruction over several seconds to obtain a single three-dimensional image.

During the last decade, real-time three-dimensional transthoracic echocardiography has also received significant attention for potential improvements in cardiac imaging. Originally developed at Duke University by von Ramm and Smith,[5–7] the current commercial system uses a two-dimensional matrix array transducer of N × N elements to steer and focus the ultrasound beam over a 65-degree pyramid to produce real-time volumetric scans at rates up to 60 volumes per second (Volumetrics Medical Imaging, [VMI] Durham, NC, USA). Real-time display options include up to five image planes oriented at any de-

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sired angle and depth within the pyramidal scan and real-time three-dimensional rendering. Clinical and animal evaluations have shown potential advantages over conventional two-dimensional scanners for measurement of ventricular volumes,[8,9] reduced scanning times in dobutamine stress echo exams,[10] measurement of peak left ventricular flow velocities,[11] and guidance of right ventricular endomyocardial biopsy.[12]

Recently, the authors have adapted the VMI real-time three-dimensional ultrasound scanner for intracardiac applications. They developed matrix array transducers operating at 5 MHz within 12 Fr catheters[13,14] and 7 MHz within 9 Fr catheters[15] in forward viewing and side scanning configurations. Using these catheter arrays, a spatial resolution of 2 mm at a depth of 2 cm in the real-time three-dimensional scans was measured. Preliminary images of cardiac anatomy were described using real-time three-dimensional ICE in the in vivo sheep model including all four chambers and valves and three-dimensional imaging of in vitro cardiac RF ablation. In addition, six electrodes were incorporated into the catheters to acquire bipolar electrograms simultaneously with the in vivo real-time three-dimensional images.[14]

This article describes a feasibility study of real-time three-dimensional ICE for the guidance of interventional electrophysiological catheters in the sheep model. The goal of the study was to visualize the cardiac vessels of interest in electrophysiological applications and the guidance of electrophysiological mapping and ablation catheters without use of fluoroscopy.

Methods

Volumetric Scanner System

The commercial VMI ultrasound scanner generates a real-time three-dimensional pyramidal scan using as many as 512 transmitters and up to 256 receive channels. The scanner uses 16:1 receive mode parallel receive processing to generate 4,100 B-mode image lines at up to 60 volumes per second. Figure 1 shows a schematic of the catheter-mounted matrix array producing the pyramidal scan with two simultaneous orthogonal B-mode image planes (perpendicular to the transducer array) and two C-mode planes (parallel to the array). Alternatively, each image plane can be inclined at any desired angle. By integrating and spatially filtering between two user selected planes (e.g., the C-mode planes) the system also displays real-time three-dimensional rendered images.

Transducer Fabrication

The transducers used in this feasibility study consist of a 13 × 11 array including 64 active channels operating at 5 MHz in a 12 Fr catheter lumen (O.D. = 3.8 mm). All transducers were constructed on a multilayer flex circuit as previously described.[15] Figure 2 shows a photograph of a selection of the catheter matrix arrays used in the current study including: a 12 Fr forward viewing catheter, 12 Fr side scanning, 12 Fr with the array oriented at 30 degrees with respect to the long axis

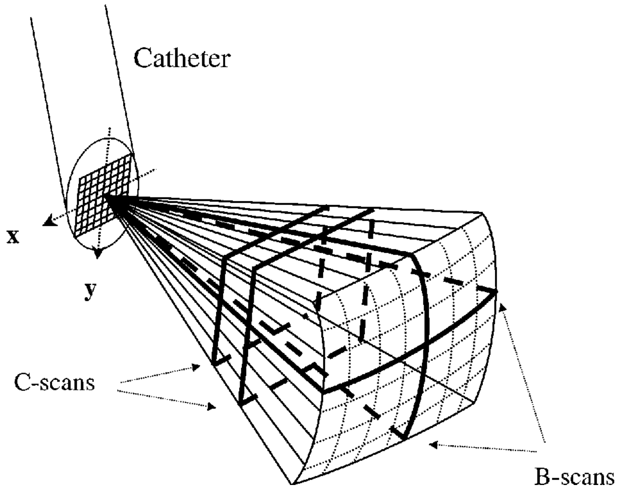

Figure 1. *Schematic of the pyramidal scan from catheter matrix array. Bold lines indicate possible display planes. By integrating and spatially filtering between two user selected planes, real-time three-dimensional rendered images are displayed.*

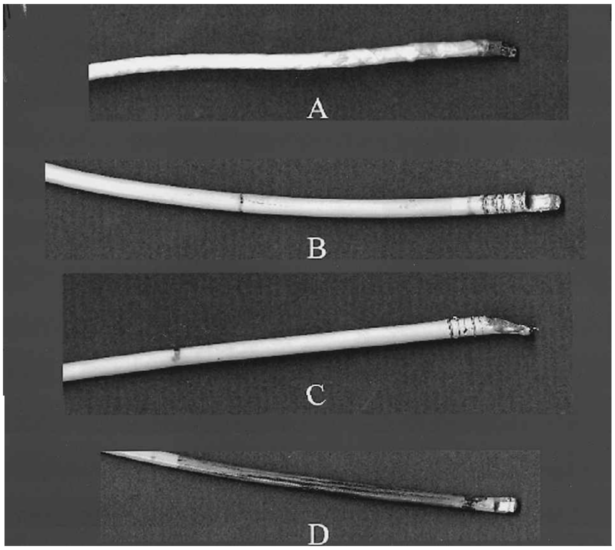

Figure 2. *Photograph of catheter matrix arrays including a (A) 5 MHz, 12 F-forward viewing, (B) 5 MHz, 12 Fr side scanning with ECG electrodes, (C) 5 MHz, 12 Fr with 30-degree bevel and ECG electrodes, and (D) 7 MHz, 9 Fr side scanning. ECG = electrocardiographic.*

of the catheter lumen (including a tip electrocardiographic [ECG] electrode and five ring electrodes), and 9 Fr side scanning catheter.

Animal Model

Three sheep were used in this study approved by the Institutional Animal Care and Use Committee at Duke University conforming to the Research Animal Use Guidelines of the American Heart Association. Anesthesia was induced with ketamine hydrochloride, 15–22 mg/kg intramuscularly (IM), and maintained with isoflurane gas (1–5%) delivered through a nose cone. After peripheral intravenous (IV) access was obtained, the animal was placed on its left side on a water-heated thermal pad. A tracheostomy was performed and the animal was mechanically ventilated with 95–99% oxygen. To prevent rumenal typany, a nasogastric tube was passed into the stomach. A femoral arterial line was placed on the left side via a percutaneous puncture. Electrolyte and respirator adjustments were made based on serial electrolyte and arterial blood gas measurements. An IV maintenance fluid with 0.9% sodium chloride was infused continuously. Blood pressure, lead II ECG, and temperature were continuously monitored throughout the procedure.

ICE

The prototype catheter transducers were not fitted with mechanical steering mechanisms. To overcome this limitation, all the in vivo images were acquired after surgery (median sternotomy or left thoracotomy) to expose the heart. Small incisions were made in the appropriate cardiac chambers to allow access of our imaging catheter. The incisions were then closed with a purse-string suture. Use of the open-chest model allowed for confirmation of the locations, orientations, and imaged structures in each experiment using manual palpation of the cardiac chambers, vessels, and the catheters therein.

ICE images included sector scans selected by the user from the pyramidal volume and real-time three-dimensional images produced by rendering the three-dimensional echo data within a volume selected by the user and denoted in the figures below by the bold arrows.

A 6 Fr quadripolar mapping catheter was used in the study (EP Technologies, Boston Scientific) which was combined with an RF ablation system (Cardiac Pathways, Model 8002, Radii T, Sunnyvale, CA, USA) to create the endocardial lesions.

Results

From Within the Left Atrium

The imaging catheter was surgically inserted into the left atrium (LA). The electrophysiological mapping catheter was inserted into the left ventricle (LV) via a surgical puncture at the apex. The tip was then moved retrogradely into the LA across the mitral valve. Figure 3A shows a single sector image selected from the pyramidal volumetric scan including the LA, atrial septum, and the right atrium (RA). It also shows a long-axis view of the mapping catheter adjacent to the septum. Figure 3A is analogous to that obtained by the conventional phased-array ICE described above. However, Figure 3B shows the simultaneous real-time three-dimensional image. The depth information in the three-dimensional image seems to contain more information yielding a better view of the catheter and the curvature of the septum.

In like manner, Figure 4 compares images of two right pulmonary veins (PVs) acquired from within the LA. The images include the initial cross-sectional sector image (Fig. 4A), the simultaneous real-time three-dimensional rendered image that shows an en face view of the PVs (Fig. 4B), the cross-sectional sector image after the electrophysiological mapping catheter was inserted into the ostium of the lower vein (Fig. 4C), and the simultaneous three-dimensional image clearly containing the mapping catheter in the lower vein (Fig. 4D). In this case, the combined simultaneous sector scan and rendered view could ease the guidance of the mapping catheter into the PV.

From the RA

More clinically relevant experiments from the RA were performed. The imaging catheter was inserted through an incision into the RA. The electrophysiological mapping catheter was inserted into the jugular vein, advanced antegradely into the superior vena cava and then into the RA. Figure 5 compares images of the coronary sinus (CS) ostium acquired from within the RA. The images include the initial cross-sectional sector image (Fig. 5A), the simultaneous real-time three-dimensional rendered image that shows an en face view of the CS (Fig. 5B), the cross-sectional image after the electrophysiological mapping catheter was inserted into the CS (Fig. 5C), and the simultaneous three-dimensional image containing the mapping catheter in the CS (Fig. 5D). Again, the combined sector scan and rendered view eased the guidance of the mapping catheter into the CS.

In a subsequent procedure, the imaging catheter was inserted into the CS from the RA and positioned posterior at the level of the mid-LA. By rotating the catheter in the superior direction, a view of the left PVs was obtained (Fig. 6) including the cross-sectional sector image (Fig. 6A) and the simultaneous en face rendered view of the PVs (Fig. 6B).

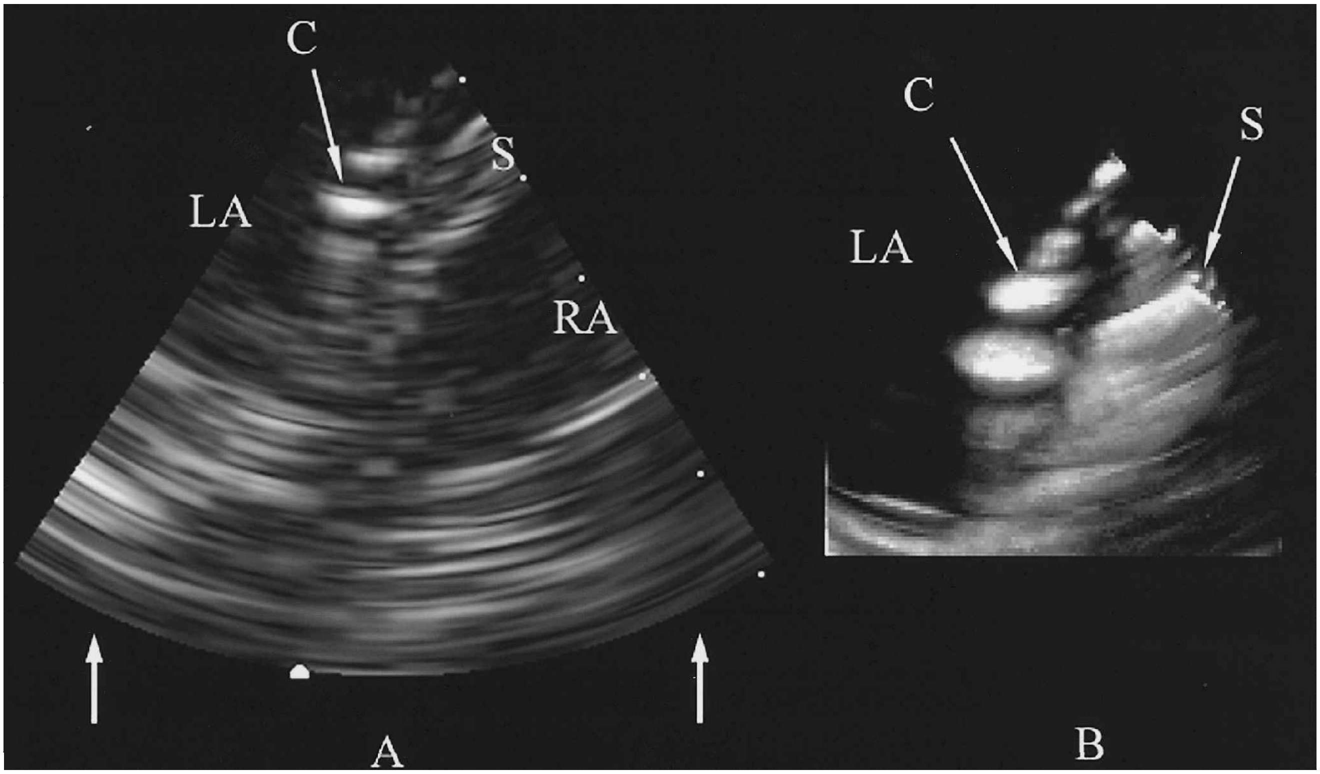

Figure 3. *Three-dimensional intracardiac echocardiographic (ICE) scan with imaging catheter in the left atrium (LA) including (A) a sector image of the LA, septum S, right atrium (RA), mapping catheter C, (B) simultaneous real-time three-dimensional image obtained by rendering the volumetric data in the pyramidal scan between the two bold arrows in (A).*

From the Right Ventricle

Figure 7 shows the result of one ablation procedure. The ablation catheter was passed antegradely from the jugular vein access, through the tricuspid valve and into the right ventricle (RV) near the apex. The imaging catheter was surgically inserted into the RV adjacent to the ablation catheter. The ventricular wall was located 1 cm from the face of the transducer. Because of this close proximity, the best slice through the pyramidal volume was selected to monitor the ablation process rather than use the real-time three-dimensional rendering feature. Figure 7A shows the image during the course of a 17-second RF ablation using an RF power of 18 W. The ablation catheter body and catheter tip is identified. Figure 7B shows the same scan immediately after an abrupt rise in the tip impedance. The created lesion is clearly more echogenic than the surrounding tissue. Figure 7C shows an optical photograph of the RV epicardial wall of the exposed heart confirming the expected location of a transmural lesion. In other similar ablation procedures the creation and ejection of microbubbles from the lesion were imaged at the time of the tip impedance rise.

Discussion

The feasibility of using real-time three-dimensional ICE for guidance of interventional electrophysiological procedures was tested. The system uses a catheter matrix array transducer and features real-time three-dimensional rendering. Real-time three-dimensional scans were obtained including cross-sectional images and simultaneous rendered views of anatomic landmarks of value in electrophysiological procedures including the PVs and CS. The real-time three-dimensional rendered images contain more information than the cross-sectional scans due to the integration over large depths inherent in the process of three-dimensional rendering. In vivo RF ablation procedures were also monitored.

The primary limitation of the current catheter transducers is the 12 Fr size that is too large for routine clinical use. The authors are actively pursuing the development of transducer ar-

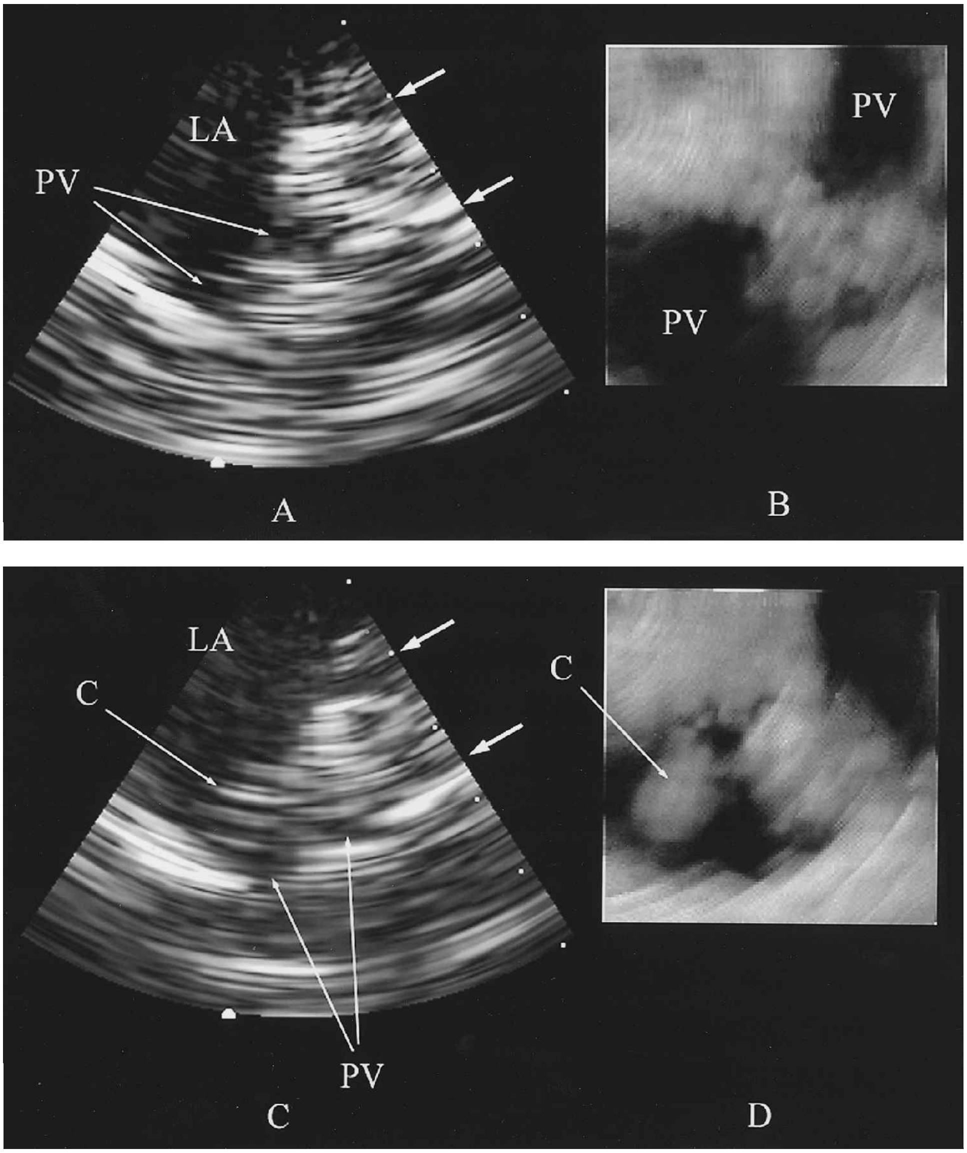

Figure 4. *Three-dimensional intracardiac echocardiographic scan with imaging catheter in the left atrium (LA) including (A) a sector image of right pulmonary veins (PVs), (B) simultaneous real-time three-dimensional rendered image of en face view of the PVs, (C) sector image of PVs with mapping catheter in the lower vein, and (D) simultaneous three dimensional image with the mapping catheter in the lower vein.*

rays in smaller catheters and have recently shown prototype devices with 70 channels in a 9 Fr lumen.[16] Another limitation is the lack of mechanical steering that would also facilitate clinical use.

To improve image quality, more transducer channels and higher frequency transducer arrays are needed. New miniature cable technology is becoming available that may allow up to 200 channels in clinical size catheters.[16,17] The authors have developed transthoracic matrix array transducers operating up to 10 MHz[18] and this technology can be extended to intracardiac catheter matrix arrays. With these improvements, they believe real-time three-dimensional ICE may well become a valuable clinical tool for the guidance of electrophysiological procedures.

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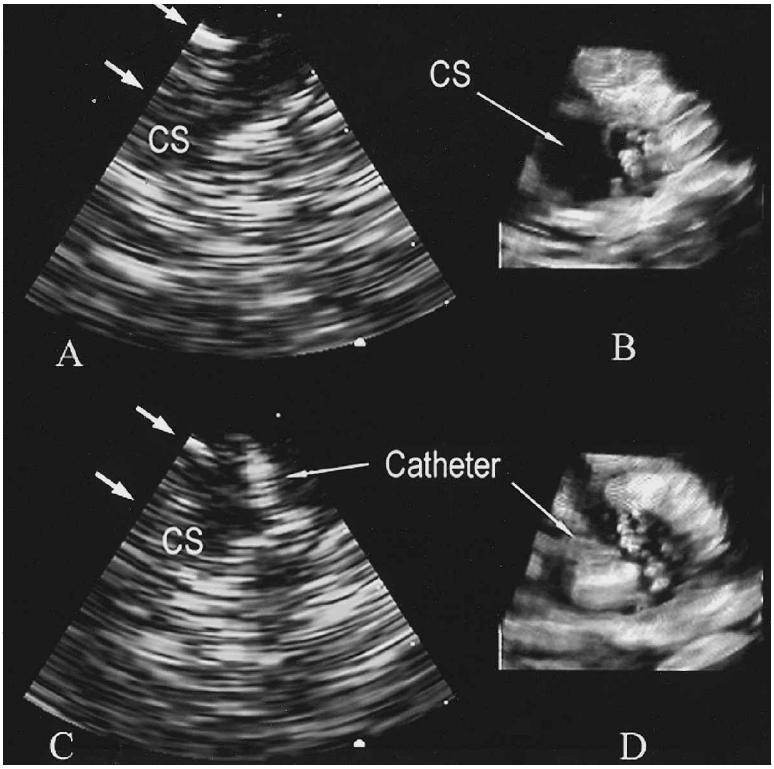

Figure 5. *Three-dimensional intracardiac electrocardiographic scan with imaging catheter in the right atrium (RA) including (A) a sector image of the coronary sinus (CS) (B) simultaneous real-time three-dimensional rendered image of an en face view of the CS ostium, (C) cross-sectional image with mapping catheter inserted into the CS, and (D) simultaneous three-dimensional image with mapping catheter in the CS.*

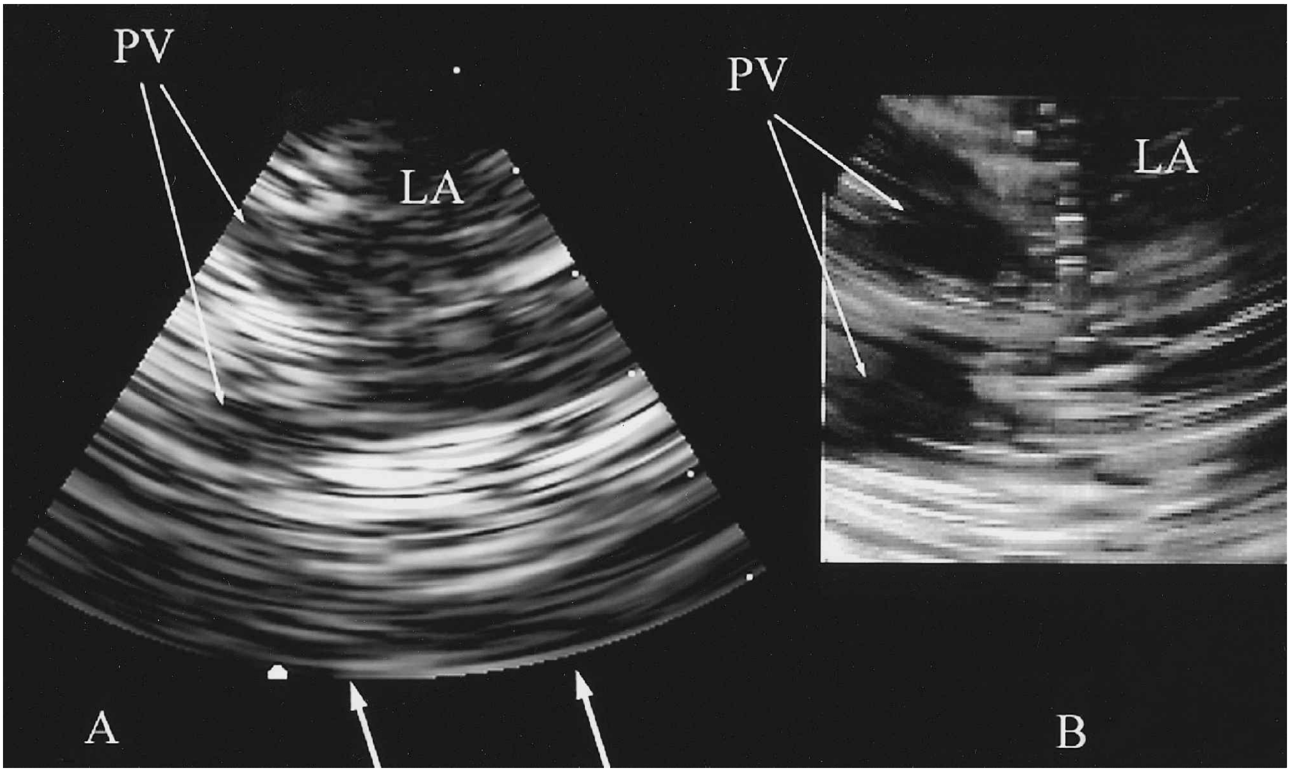

Figure 6. *Three-dimensional intracardiac echocardiographic scan with an imaging catheter in the coronary sinus (CS) including (A) a sector image of the left pulmonary veins (PVs), (B) simultaneous real-time three-dimensionally rendered image of an en face view of the PVs.*

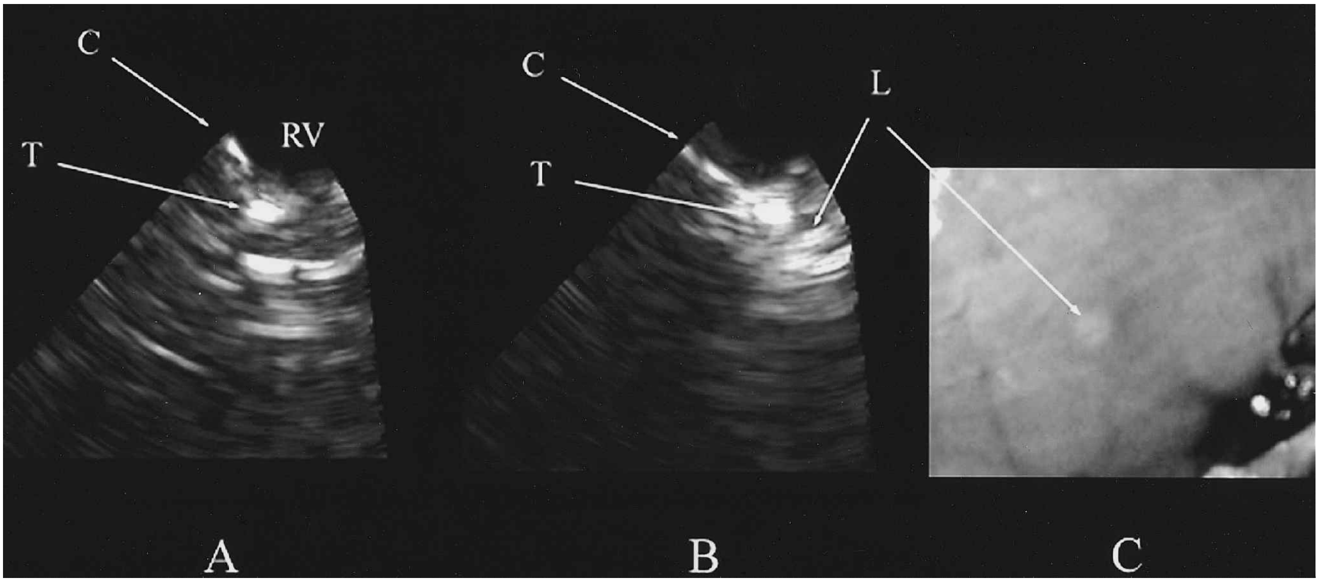

Figure 7. *Three-dimensional intracardiac electrocardiographic scan of radiofrequency ablation with the imaging catheter in the right ventricle (RV) including a (A) real-time user selected scan of the RV during ablation with the catheter shaft C and catheter tip T, (B) scan of lesion L at the end of ablation, and (C) photograph of RV epicardial wall with transmural lesion L.*

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