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Application of 3-Dimensional Computed Tomographic Image Guidance to WATCHMAN Implantation and Impact on Early Operator Learning Curve

Single-Center Experience

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ABSTRACT

OBJECTIVES The aim of this study was to examine the impact of 3-dimensional (3D) computed tomographic (CT) guided procedural planning for left atrial appendage (LAA) occlusion on the early operator WATCHMAN learning curve.

BACKGROUND Traditional WATCHMAN implantation is dependent on 2-dimensional transesophageal echocardiographic (TEE) sizing and intraprocedural guidance.

METHODS LAA occlusion with the WATCHMAN device was performed in 53 patients. Pre-procedural case plans were generated from CT studies with recommended device size, catheter selection, and C-arm angle for deployment.

RESULTS All 53 patients underwent successful LAA occlusion with the WATCHMAN. Three-dimensional CT LAA maximal-width sizing was 2.7 ± 2.2 mm and 2.3 ± 3.0 mm larger than 2-dimensional and 3D TEE measurements, respectively ($p \leq 0.0001$). By CT imaging, device selection was 100% accurate. There were 4 peri-WATCHMAN leaks (<4.5 mm) secondary to accessory LAA pedunculations. By 2-dimensional TEE maximal-width measurements alone, 62.3% (33 of 53) would have required larger devices. Using 3D TEE maximal-width measurements, 52.8% of cases (28 of 53) would have required larger devices. Three-dimensional TEE length would have inappropriately excluded 10 patients from WATCHMAN implantation. Compared with the average of 1.8 devices used per implantation attempt in PROTECT AF (WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation) (82% success rate), the present site averaged 1.245 devices per implantation attempt (100% success rate). There were no intraprocedural screen failures and no major adverse cardiac events.

CONCLUSIONS Three-dimensional CT image case planning provides a comprehensive and customized patient-specific LAA assessment that appears to be accurate and may possibly facilitate reducing the early WATCHMAN implantation learning curve. (J Am Coll Cardiol Intv 2016;9:2329–40) © 2016 by the American College of Cardiology Foundation.

Standard procedural guidance and device selection for the WATCHMAN left atrial appendage (LAA) closure device is based on 2-dimensional (2D) transesophageal echocardiographic (TEE) guidance (1). However, in the early WATCHMAN clinical trials, on average 1.8 devices were used per patient to achieve adequate device sealing, illuminating the accuracy limitations of 2D TEE imaging for characterizing the LAA (2). Incentives for increased accuracy include reducing device exchanges and catheter and

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ABBREVIATIONS AND ACRONYMS

CT = computed tomographic

LAA = left atrial appendage

TEE = transesophageal echocardiographic

3D = 3-dimensional

2D = 2-dimensional

contrast use, therefore minimizing the opportunity for complications (1).

Recent device development for LAA occlusion has led us to recognize the unique and varied morphology of the LAA (3). This morphological complexity may be underappreciated using 2D modalities, and 3-dimensional (3D) characterization may provide similar benefits to device sizing and procedure planning as demonstrated in transcatheter heart valve therapy (4). Furthermore, planning of spatial navigation through the left atrium requires a unique perspective likely best replicated by 3D imaging.

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In our study, we examined the differences of computed tomographic (CT) versus 2D and 3D TEE sizing of the LAA and the impact of 3D CT guidance on WATCHMAN device implantation.

METHODS

Between May 2015 and February 2016, 53 consecutive patients underwent LAA WATCHMAN implantation at Henry Ford Hospital by the Center for Structural Heart Disease. All patients underwent pre-procedural CT imaging of the LAA, followed by intraprocedural echocardiographic characterization and guidance with 2D and 3D TEE imaging.

CT IMAGE ACQUISITION AND POST-PROCESSING SOFTWARE. Pre-procedural imaging involved a contrast-enhanced, retrospectively electrocardiographically gated CT angiographic acquisition without electrocardiographic dose modulation using a GE Discovery CT750 (GE Healthcare, Waukesha, Wisconsin). Iodinated contrast, Isovue 370 (Bracco Diagnostics, Patheon Italia, Ferentino, Italy) was injected at a rate of 4 ml/s, for a total volume of 80 ml, through an 18-gauge peripheral intravenous line. Tube current and voltage settings were adapted from traditional CT angiographic gating protocols, adjusted for body mass index.

After image acquisition, CT Digital Imaging and Communications in Medicine data were analyzed using Vitrea (Vital Images, Minnetonka, Minnesota) and Mimics (Materialise, Leuven, Belgium). All pre-procedural imaging, planning, computer-aided design analysis, and 3D printing were performed on site at Henry Ford Health System in partnership with the Henry Ford Innovation Institute.

Using a 5% to 95% reconstructed valve cine series of the CT study, the LAA is analyzed in 10% reconstructed R-R intervals to enable selection of the mid to late ventricular systolic phase that corresponds with maximal end-diastolic filling for the LAA. Raw CT Digital Imaging and Communications in Medicine data containing the aforementioned diastolic phase of the LAA are then exported to specialized computer-aided design segmentation software (Mimics), with which the blood volume of the left atrium, LAA, aortic annulus, and rims of the superior vena cava and inferior vena cava are manually segmented and 3D-printed by 2 industrial designers (M.F., E.M.).

The LAA orifice was defined as the plane connecting the pulmonary vein ridge superiorly to the inferior junction of the left atrium and the LAA at the level of the circumflex artery. The LAA landing zone is defined as the entryway into the main lobe of the LAA, where a potential LAA device could comfortably and safely be seated within the confines of the body of the appendage. On multiplanar CT reconstruction, this is commonly demarcated using a double-oblique method by placing the crosshairs at the level of the takeoff of the proximal left circumflex artery from the left anterior descending artery extending, and then by rotating the coronal and sagittal crosshairs sequentially to align their crosshairs to run parallel to the course of the main lobe of the LAA (**Table 1**). If the LAA ostium is ambiguous, a physical WATCHMAN device is implanted ex vivo in the patient's 3D-printed LAA to test-fit the device to approximate the device landing zone (**Table 1**). Maximal and minimal diameters and area of the LAA landing zone are measured (**Table 1**). Device size is determined by the widest diameter of the landing zone measured by CT imaging and selection according to the WATCHMAN instructions for use. Maximal length of the LAA was defined as the linear distance from the center of the true ostium of the LAA landing zone to the distal terminus of the main lobe of the appendage (**Figure 1**).

Once the WATCHMAN device size has been chosen, the depth necessary for device deployment is known (equivalent to the width of the WATCHMAN device). This length is drawn from the center of the landing zone toward the main lobe of the distal tip of the LAA and then projected into inverted maximal-intensity projections with the 3D crosshairs overlay showing both the landing zone and device surface as a single 2D plane (**Figure 2**). This inverted maximal-intensity projection is applied to simulate the LAA intraprocedural angiogram, to anticipate the necessary C-arm angles, depth of deployment, and catheter tip positioning for maximal device implant coaxiality to the LAA.

INTRA-PROCEDURAL TEE GUIDANCE. Intraprocedural TEE imaging was performed using a Philips CX50 echocardiograph and an X7-2T TEE probe

(Philips Medical Systems, Andover, Massachusetts). Three-dimensional and 3D TEE measurements were performed after an LAA mean pressure >10 mm Hg. Baseline measurements of the LAA landing zone diameter and depth were recorded at 0°, 45°, 90°, and 135°. Three-dimensional TEE measurements were performed intraprocedurally on the CX50 using the 3D TEE software QLAB version 9.0 (Philips Medical Systems). With the aid of the 3D printout, meticulous care was taken to ensure that similar landing zones were obtained on 2D and 3D TEE imaging compared with CT imaging for device sizing. Computer-generated deployment sheath simulations were then modeled from the CT volumetric dataset in the 2D TEE 45° and 2D TEE 135° views to project the landing zone appearance on TEE imaging and for maximal device and catheter coaxiality positioning to the main lobe of the LAA (Figure 3).

STATISTICAL ANALYSIS. Paired *t*-test and analysis of variance were used to evaluate for statistical significance between 2D and 3D TEE and CT measurements. Degree of correlation was calculated using the Pearson correlation coefficient (*r* value) in SAS version 9.4 (SAS Institute, Cary, North Carolina). Statistical significance was defined as $p < 0.05$. The Bland-Altman method was used to describe the mean difference between 2 modalities. For comparison of major adverse events, patient procedural outcome data from the PROTECT AF (WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation), CAP (Continued Access to PROTECT AF), PREVAIL (WATCHMAN LAA Closure Device in Patients With Atrial Fibrillation Versus Long Term Warfarin Therapy), and CAP2 (Continued Access to PREVAIL) trials were collected and analyzed against data from our study using 2-sample *z* tests for proportions.

RESULTS

From May 2015 through February 2016, 53 consecutive patients underwent successful WATCHMAN implantation (Table 2).

DEVICE SIZING. Compared with 2D and 3D TEE sizing, 3D CT maximal width of the LAA landing zone was larger ($p \leq 0.0001$). The mean difference between 3D CT maximal LAA width and 2D TEE measurements was 2.7 ± 2.2 mm, with an intraclass correlation coefficient of 0.77 and a Pearson correlation coefficient <0.001 (Figure 4). The mean difference between 3D CT maximal LAA width and 3D TEE measurements was 2.3 ± 3.0 mm, with an intraclass correlation coefficient of 0.86 and a Pearson correlation coefficient <0.001 (Figure 5). In analyzing the maximal length of the LAA from identified device landing zone to the tip of the main lobe of the appendage, CT sizing of the maximal length was larger than both 2D and 3D TEE sizing ($p \leq 0.0001$). The mean difference of 3D CT and 2D TEE maximal LAA length measurements was 4.0 ± 5.8 mm, with an intraclass correlation coefficient of 0.97 and a Pearson correlation coefficient <0.001 (Figure 6).

By 2D TEE maximal width, 62.3% of the patients (33 of 53) would have received the incorrect device and required upsizing to a larger device size intraprocedurally. By 3D TEE maximal width, 52.8% of the patients (28 of 53) would have been undersized and required upsizing to a larger device intraprocedurally.

CLINICAL IMPACT. All 53 patients underwent successful device implantation. There were no screen failures. If traditional 2D TEE maximal-width dimensions had been applied to this study population, 3 patients would have been excluded from LAA occlusion intraprocedurally because of 2D TEE undersizing. If 3D TEE maximal width had been applied to this study population, 3 patients would have been excluded from LAA occlusion, the first 2 because of 3D TEE undersizing of the LAA and the latter because of misidentification of the LAA landing zone and oversizing of the LAA into the left atrium, exceeding available device sizes. By maximal length of LAA measurements, intraprocedural 2D TEE maximal length would have screen-failed 18.9% of the patients (10 of 53) from WATCHMAN candidacy. Of these 53 patients, there were 4 peri-WATCHMAN leaks, each <4.5 mm in width. Two of the 4 peri-WATCHMAN leaks were anticipated because of the presence of LAA trabeculations; the remaining 2 were secondary to device positioning.

PROCEDURE-RELATED SAFETY EVENTS: ELIMINATION OF EARLY IMPLANTER LEARNING CURVE. Compared with PROTECT AF, CAP, PREVAIL, and CAP2 major adverse cardiac events, all of our patients underwent successful device implantation (Table 3) (1,5). Total procedure time in the first 3 patients at our new implanting site was 48 ± 11 min, 34 min faster than the first 3 patients at each new implanting site in the first half of the PROTECT AF trial and 7 min faster compared with the rest of the PROTECT AF study (Table 4) (2,5).

In all 53 cases, only 1 device size was used for each case. Compared with the first half of PROTECT AF, in which an average of 1.8 devices were used

TABLE 1 CT Based Left Atrial Appendage Case Plan Protocol

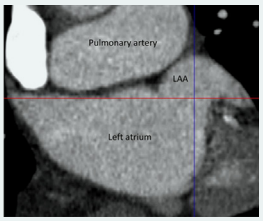
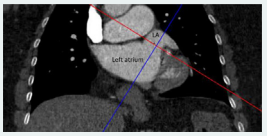
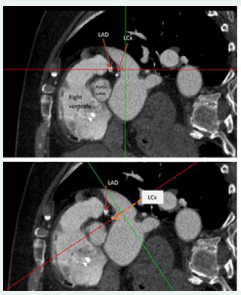
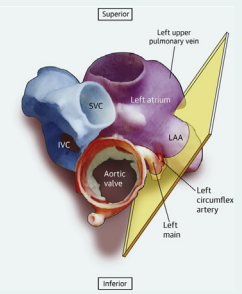
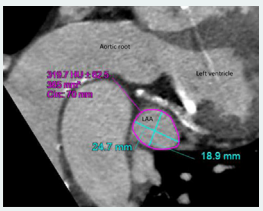
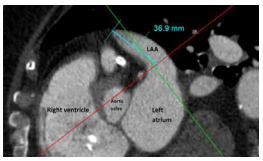
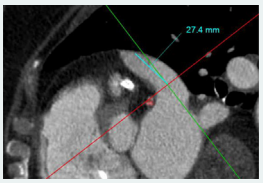
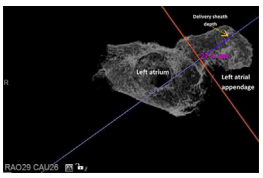
Steps	In-Depth Description	Example Images
Sizing the LAA landing zone	Load the 0%–95% valve series of the LAA into CT viewer. Identify the phase that corresponds to mid to end LV systolic filling that corresponds best to maximal LAA end-diastolic filling. In the coronal cross sections, place the crosshairs on the LAA.	
	In a curved multiplanar reformat plane, within the coronal window, double-oblique the sagittal crosshairs (**blue**) to the direction of the main lobe of the LAA.	
	In the sagittal window, within a curved multiplanar reformat plane, advance the crosshairs to the level of the proximal LCx artery takeoff from the LAD. Then, double-oblique the coronal crosshairs (**green**) to the direction of the main lobe of the LAA (commonly runs parallel to the course of the LAD).	 
	On the axial cross sections, measure the maximal and minimal diameters, area, and circumference of the LAA landing zone.	
Identifying the maximal length of the LAA landing zone to distal tip of the main lobe of the LAA	Identify the maximal length or depth of the LAA from the landing zone to the distal LAA tip of in the sagittal and coronal views, and record the largest value. (Scroll in and out of the identified view to ensure maximal length is accounted for.)	
Generating the length of the WATCHMAN delivery sheath	Adjust the length measurement to equal the maximal width of the WATCHMAN device selected (per the sizing guidelines from the WATCHMAN DFU). In this patient, a 24.7-mm maximal-width diameter corresponds to selection of a 27-mm WATCHMAN device, and hence delivery sheath depth of ~27 mm (±0.5 mm to account for distal delivery tip plastic tricut length and presence or absence of LAA pedunculations protruding into site of catheter positioning).	
C-arm angles	Segment the LAA, left atrium, into a transparent 3D volume image. In the 3D window, align the axial **(red)** and sagittal **(blue)** planes to intersect perpendicular to each other. Show the delivery sheath length in the 3D image **(pink line)**.	

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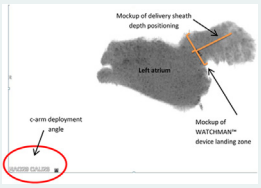
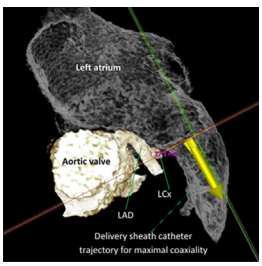
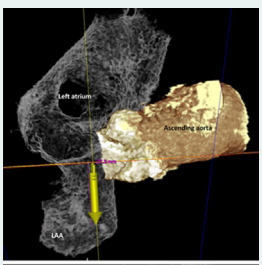
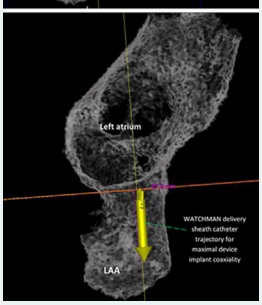
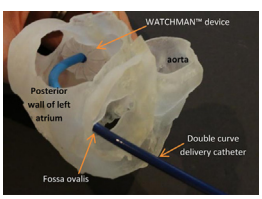
TABLE 1 Continued

Steps	In-Depth Description	Example Images
Implanter case plan	Apply inverted MIP to the 3D volume to project the 3D image in a black-and-white radiographic simulation. Load the image screenshot into Microsoft PowerPoint, apply "insert art tool," and overlay the crosshairs with a bracket and line (over the demarcated delivery sheath) to simulate the WATCHMAN device landing zone and delivery sheath depth positioning.	
Interventional imaging case plan (TEE 45° view)	Segment the aortic annulus, proximal LAD and LCx into the 3D volume. Adjust the image to bring the aortic valve centered and anterior. Adjust the axial **(red)** and coronal **(green)** crosshairs to intersect perpendicular to each other. The **yellow arrow** depicts delivery sheath positioning when imaging in the 2D TEE midesophageal short-axis view of the aortic valve.	
TEE 135° view	Rotate the 3D image along the sagittal plane **(red crosshairs)** until the aorta is at 3 o'clock and anterior to the LAA. Remove the aortic root from the 3D volume. With the LAA pointing towards 6 o'clock, the **yellow arrow** depicts the delivery catheter and sheath tip position for maximal catheter coaxiality to optimize WATCHMAN implantation. The sagittal plane **(red crosshairs)** now depicts the landing zone to be shown by 2D TEE in the 135° view.	 
3D printout assisted type of delivery catheter (single, anterior, double curve) selection	3D printouts of patient's specific left atrial, LAA anatomy were generated to assist in bench-test selection of catheter curvature for device implantation.	

CT = computed tomographic; DFU = directions for use; LA = left atrium; LAA = left atrial appendage; LAD = left anterior descending coronary artery; LC = left circumflex coronary artery; LCx = left circumflex coronary artery; LV = left ventricular; MIP = maximal=intensity projection; TEE = transesophageal echocardiographic; 3D = 3-dimensional; 2D = 2-dimensional.

per implantation attempt with an 82% implantation success rate, our site averaged 1.245 devices per implantation attempt with a 100% implantation success rate. Of 53 patients, 7 were outliers, accounting for more than 1 device used on average. In 6 of these 7 patients, more than 1 device was used because of difficult transseptal crossing and difficulty in obtaining catheter device coaxiality for

FIGURE 1 Defining the Left Atrial Appendage Landing Zone

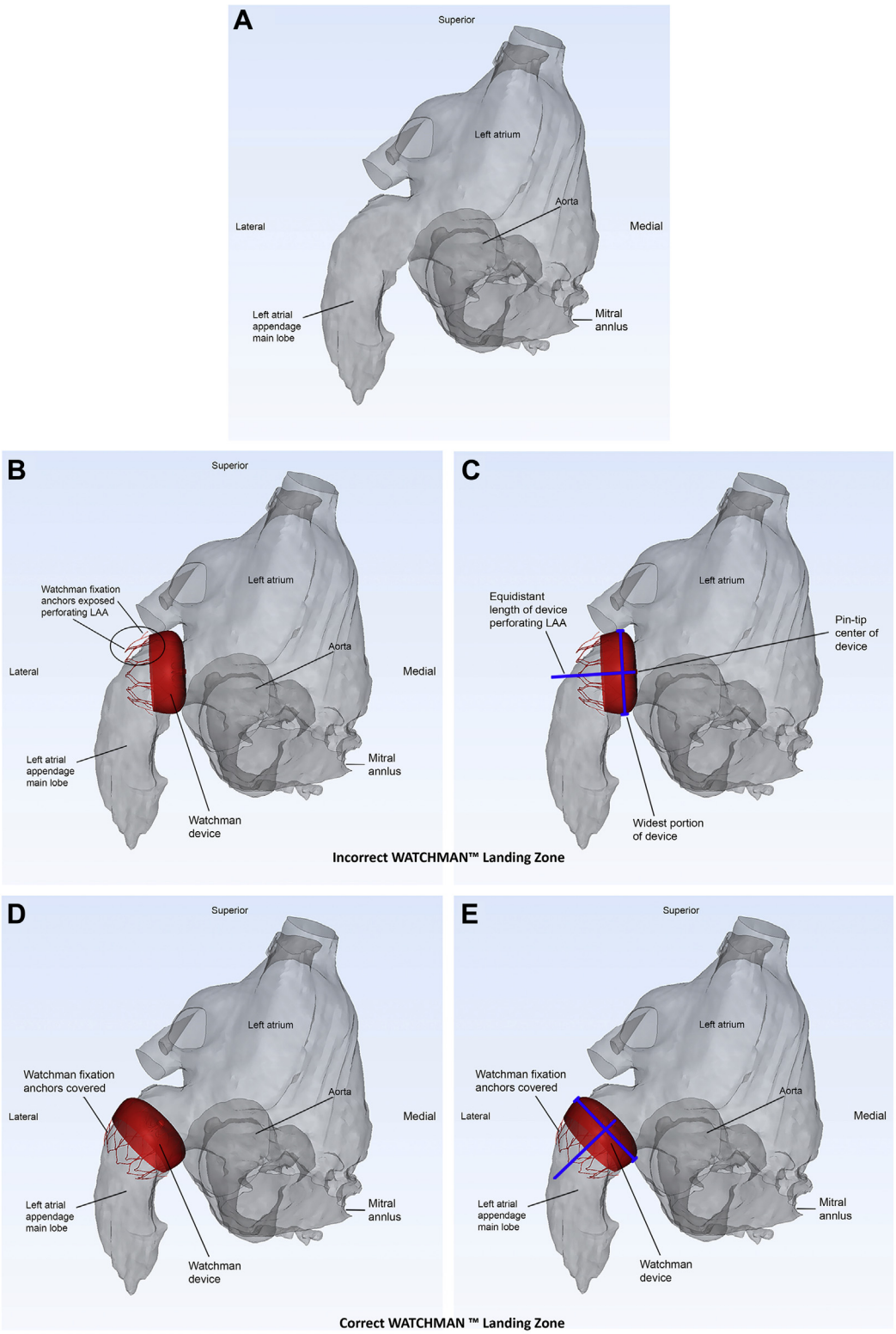


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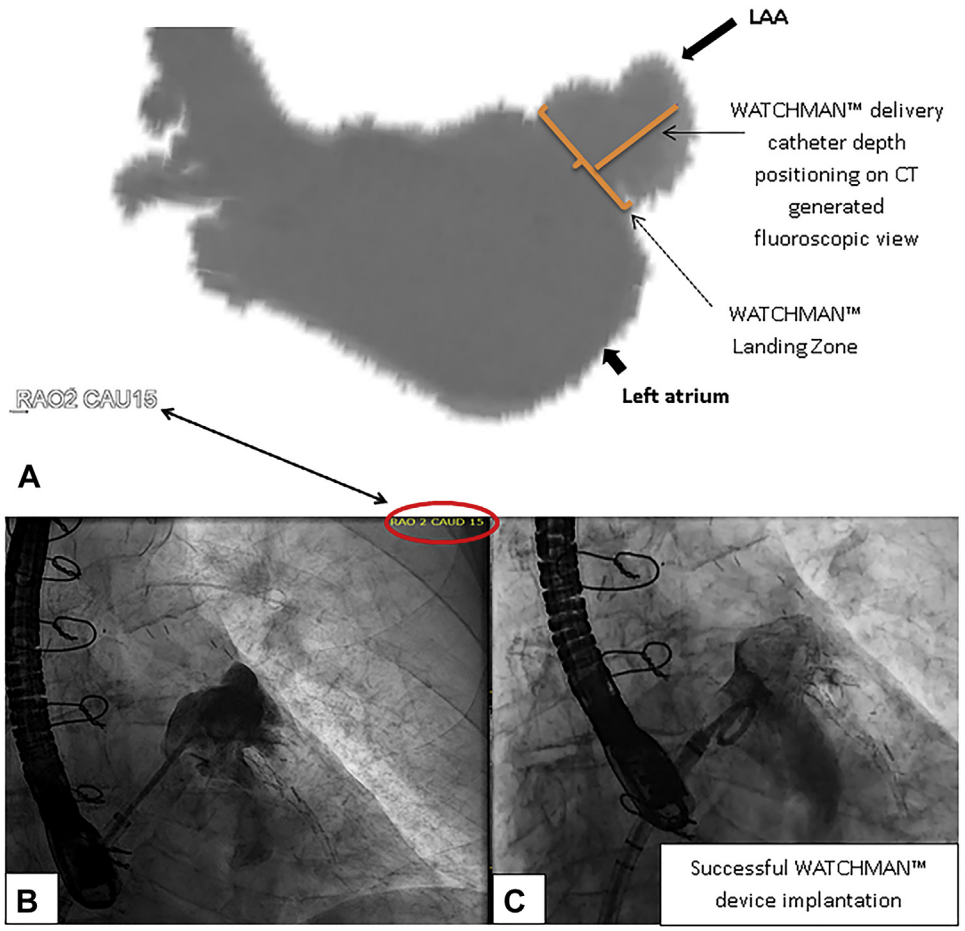
FIGURE 2 Computed Tomographic Case Plan for Intraprocedural Left Atrial Appendage C-Arm Fluoroscopic Imaging

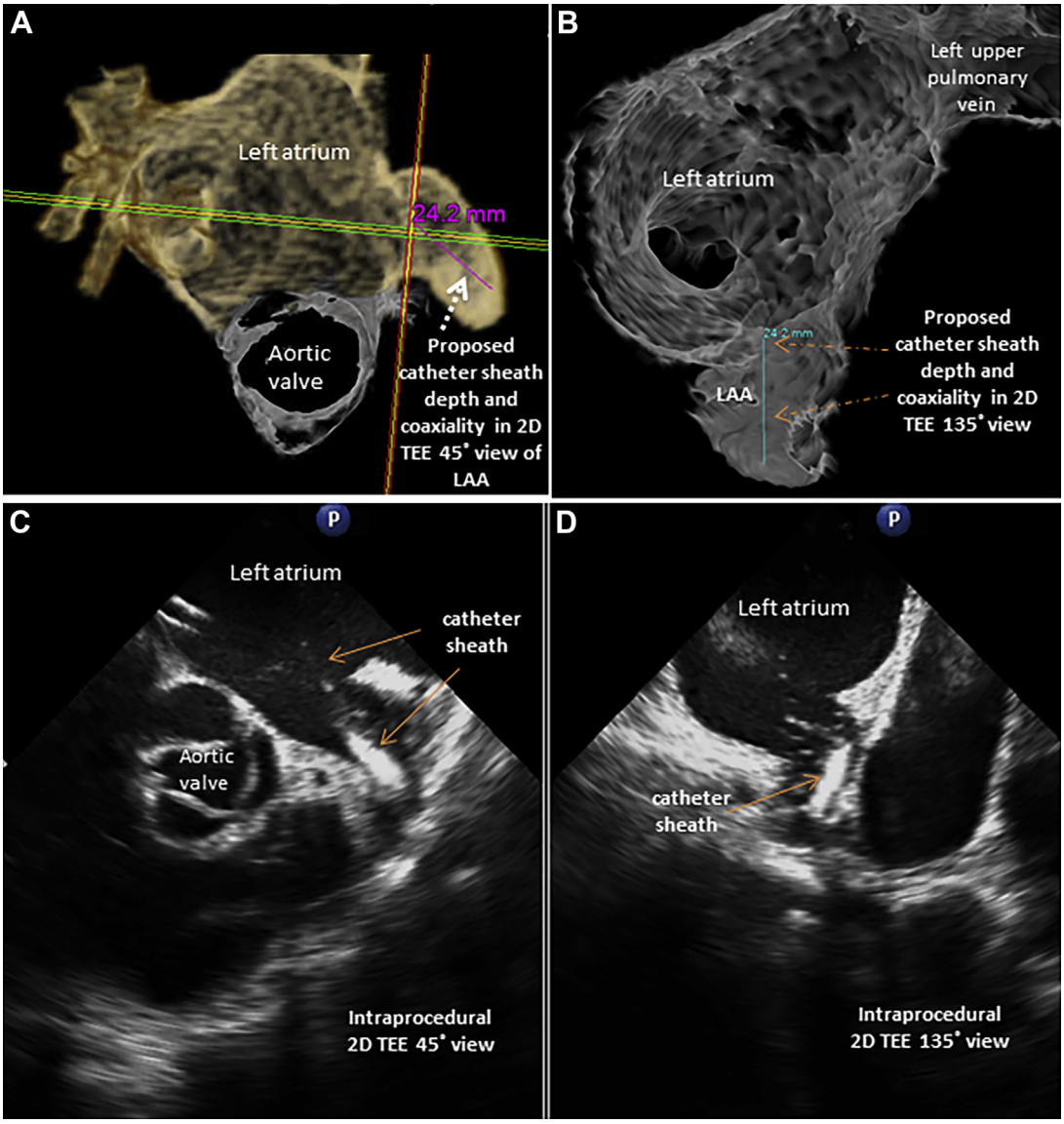


After sizing and depth analysis are completed for the left atrial appendage (LAA) landing zone, the LAA, left atrium, and any pertinent adjacent anatomic landmark structures (transcatheter valves, sternotomy wires, circumflex artery coronary stents, etc.) are segmented and projected into inverted maximal intensity projection to simulate the intraprocedural LAA angiogram **(A)**. Appropriate C-arm angles are generated and demonstrated on the actual day of a successful procedural implantation with baseline LAA angiography at those angles and final device implantation corresponding to the mockup case plan provided by computed tomography **(B,C)**.

FIGURE 1 Continued

The mid to end left ventricular systolic phase corresponding to maximal left atrial appendage (LAA) diastolic filling is identified and segmented into a computer-aided design 3-dimensional (3D) volume image of the patient's specific anatomy **(A)**. Traditional sizing of the LAA typically occurs at the junction between the left atrium (LA) and LAA interface. However, this is the incorrect landing zone for most WATCHMAN implantations **(B)**. Sizing the device to the junction of the LA and the LAA and then virtually implanting that sized device in the patient's specific heart demonstrates that the device would cause perforation of the LAA, as there is insufficient depth to implant the device, thereby causing the WATCHMAN fixation anchors to puncture the LAA because of the patient's specific LAA angulation. The concept of using a letter "T" (with equal width and length) to simulate the WATCHMAN device without physically implanting the actual model illustrates the same concerns **(C)**. Once the main lobe of the LAA is identified, and the WATCHMAN device positioning is adjusted to be parallel to the blood flow of the main lobe of the LAA, computer-aided design modeling demonstrates that there is sufficient depth and supporting circumferential LAA tubular scaffolding to implant the WATCHMAN device at the corrected landing zone. Again, the concept of the letter "T" demonstrates that there is equal width and depth to ensure that: 1) all WATCHMAN fixation anchors are covered within the lumen of and in contact with the inner surface of the LAA; 2) there is a sufficient seal around the cap of the device; and 3) major outpouchings or pedunculations are covered inferior to the device landing zone **(D)**.

FIGURE 3 Computed Tomographic Case Plan for Intraprocedural Left Atrial Appendage Transesophageal Echocardiographic Imaging Guidance



The 2 most important views for WATCHMAN implantation, the 2-dimensional (2D) transesophageal echocardiographic (TEE) 45° and 135° views, are segmented by computed tomography. The previously identified necessary depth of deployment for the device size chosen is projected with a 3-dimensional (3D) straight line into the 3D transparent volume image of the LAA to demonstrate catheter positioning **(A,B)** as it would appear on the corresponding intraprocedural 2D TEE 45° and 135° views **(C,D)**. In complex anatomies, this helps identify if the correct delivery sheath catheter tip is being selected to obtain the distal portion catheter tip coaxiality necessary as defined by the 3D computed tomographic volumetric dataset. Additionally, the computed tomography–generated delivery catheter positioning on 2D TEE imaging helps guide intraprocedural device and catheter positioning to minimize device pop-out and peri-WATCHMAN leak (the latter secondary to canted device delivery).

deployment. The seventh patient had 3 devices of the same size used secondary to difficulty achieving device deployment at the necessary landing zone depth because of the presence of prominent intra-LAA trabeculations.

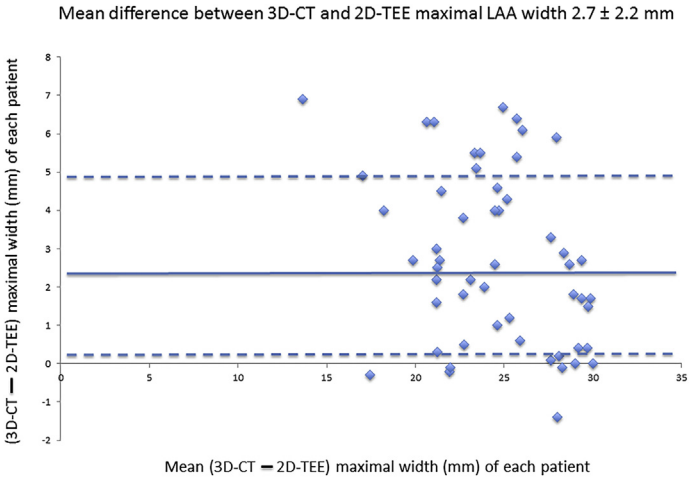
There were no major cardiovascular events, specifically no pericardial effusions, cardiac ruptures, or device embolizations or migrations. There was 1 thrombus formation post-device implantation observed on 1-month post-implantation CT follow-up.

TABLE 2 Patient Baseline and Procedural Characteristics (n = 53)

Age, yrs	77.5 ± 7.7
Men	31
Heart failure	28
Hypertension	48
Diabetes mellitus	22
Prior stroke or TIA	22
Coronary heart disease	36
Chronic renal failure	21
Prior major bleed*	32
Prior transfusion	16
$CHADS_2$ score	3.2 ± 1.2
CHA_2DS_2-VASc score	5.3 ± 1.4
HAS-BLED score	3.6 ± 1.3
LA mean pressure, mm Hg	15.830 ± 4.999

Values are mean ± SD or n. *Defined as any bleeding requiring hospitalization or causing a decrease in hemoglobin level >2 g/dl, and/or requiring blood transfusion of ≥2 U of blood, and/or intracranial bleed (12).

FIGURE 4 Mean Difference Between 3-Dimensional Computed Tomographic and 2-Dimensional Transesophageal Echocardiographic Maximal Left Atrial Appendage Width



DISCUSSION

Our study demonstrates the added value of 3D CT guided case planning in simplifying the WATCHMAN implantation process, providing a high level of device selection accuracy and spatial planning to simply guide catheter selection. We found CT screening for the maximal width of the LAA to be 100% accurate, and the extra WATCHMAN devices used were as a result of full device recapture for inaccurate deployment. Additionally, the combination of correct device selection, 3D print modeling, and CT spatial planning for guide catheter selection was able provide early implantation efficiency (48 ± 11 min). Whether or not planning and simplification of the procedure improved safety is speculative; in theory, reduction of device and catheter exchanges would eliminate opportunities for complications such as cardiac perforation and air and possibly device embolization. Given the widely available technology of cardiac CT, planning to this level of detail may further increase safety for the implantation of not only the WATCHMAN but the growing array of devices available for the LAA.

Our data reinforce the advantages of using a high-resolution volumetric dataset to characterize the LAA. Post-implantation CT imaging showed greater appreciation for leaks relative to TEE imaging, highlighting possible blind spots in TEE interrogation of the LAA (6). The first use of CT imaging to define the LAA involved a 16-slice scanner and found that the segmented CT images yielded larger measurements than both planar and TEE measurements (7). Recent data using modern scanners found the maximal LAA width to be 25.8 ± 4.7 mm on CT imaging versus 25.1 ± 4.4 mm on TEE imaging (p = 0.016), corroborating our own findings (8).

In our analysis, although the measurements from CT imaging and the gold standard of 2D TEE imaging had reasonable agreement, analysis with the calculation of the Pearson correlation coefficient showed that there was a difference when sizing by CT versus TEE measurement for the LAA (Pearson correlation coefficient <0.001). This difference was significant

FIGURE 5 Mean Difference Between 3-Dimensional Computed Tomographic and 3-Dimensional Transesophageal Echocardiographic Maximal Left Atrial Appendage Width

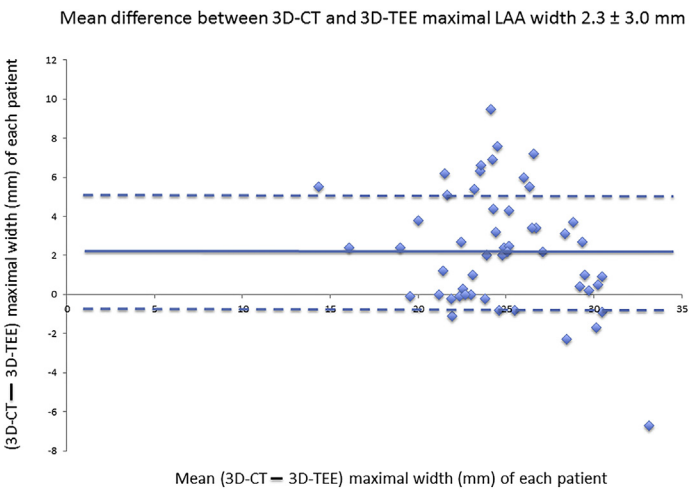
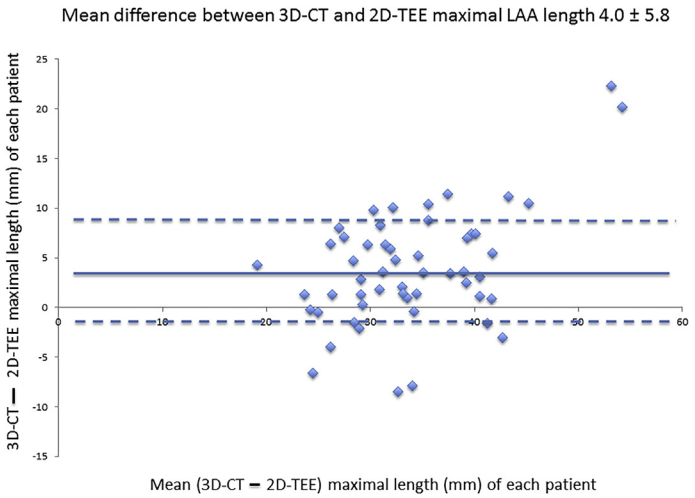


FIGURE 6 Mean Difference Between 3-Dimensional Computed Tomographic and 2-Dimensional Transesophageal Echocardiographic Maximal Left Atrial Appendage Length



enough between these 2 imaging modalities to directly affect device size selection for LAA WATCHMAN implantation. The intraclass correlation coefficient was high, as we were comparing 2 imaging methods; however, CT imaging showed larger sizes than 2D and 3D TEE imaging. A high correlation is usually expected when comparing similar but slightly different imaging modalities. Hence, a high correlation does not imply good agreement.

By noninvasive laboratory practices, patients are volume-depleted for outpatient TEE studies, as they must fast for 6 h prior to a TEE procedure and 12 h before a cardiac catheterization procedure. LAA size is heavily dependent on adequate pre-load, and hence pre-procedural outpatient TEE imaging greatly undersizes the true LAA dimensions (9). Our study is the first to demonstrate that despite adequate intra-procedural LAA loading conditions (LA mean pressure >10 mm Hg), 2D and 3D TEE imaging still undersizes the LAA compared with CT imaging.

Beyond volume loading, LAA contractility affects sizing (8,10). A gated CT scan's high spatial resolution allows visualization of LAA motion during the cardiac cycle and obtaining maximal LAA dimensions in left ventricular end-systole and minimal dimensions in left ventricular end-diastole. This is not readily appreciated on 2D TEE imaging, because of poor spatial resolution.

Successful implantation of the WATCHMAN device depends on accurate sizing of the LAA landing zone and positioning of the catheter at the correct depth for device unsheathing (1,11). The length characterization by CT imaging differed significantly from that by 2D TEE imaging (mean difference 4.0 ± 5.8 mm), illustrating a significant liability of 2D TEE imaging for case planning. Because the relative depth-to-width ratios are critical in understanding WATCHMAN implantation feasibility and success, given the unpredictability of LAA morphology, a comprehensive imaging modality with high spatial resolution is vital.

Given the questionable accuracy of TEE imaging, we maintain that high-resolution volumetric imaging with CT should be the preferred method to mitigate improper sizing that could lead to peri-WATCHMAN leak, device embolization, and potentially other major adverse catastrophic events. Notably, applying the WATCHMAN U.S. Food and Drug Administration-approved directions for use to CT sizing for use is safe, as there were no pericardial effusions post-implantation or device embolizations. Incorporation of a comprehensive 3D CT case plan analysis not only leads to fewer devices used per implantation procedure but may improve

TABLE 3 Clinical Impact of 3-Dimensional Computed Tomographic Procedural Case Planning in Eliminating Early WATCHMAN Operator Learning Curve

	PROTECT AF (n = 463)	CAP (n = 566)	PREVAIL (n = 269)	CAP2 (n = 579)	Study Site Integrating CT LAA Case Plan (n = 53)
Pericardial effusion with cardiac tamponade	13 (2.8)	7 (1.2)	4 (1.5)	8 (1.2)	0 (0.0)
Device embolization	3 (0.6)	1 (0.2)	2 (0.7)	0 (0.0)	0 (0.0)
Pericardial effusion, no intervention	4 (0.9)	5 (0.9)	0 (0.0)	3 (0.5)	0 (0.0)
Cardiac perforation (surgical repair)	7 (1.5)	1 (0.2)	1 (0.4)	3 (0.5)	0 (0.0)
Device migration	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Device thrombus	2 (0.4)	1 (0.2)	1 (0.4)	5 (0.9)	1 (2.4)

Values are n (%).

CAP = Continued Access to PROTECT AF; CAP2 = Continued Access to PREVAIL; CT = computed tomographic; LAA = left atrial appendage; PREVAIL = WATCHMAN LAA Closure Device in Patients With Atrial Fibrillation Versus Long Term Warfarin Therapy; PROTECT AF = WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation.

TABLE 4 Single-Center New Implanter WATCHMAN Procedure Major Adverse Cardiac Outcomes Compared With WATCHMAN Clinical Trials

	PROTECT AF		PROTECT AF		CSHD 3D CT Guided New Implanting Site	p Value (vs. First Half of PROTECT AF Trial)
	First Half of Trial	Second Half of Trial	First 3 Patients	Other Patients		
Implantation success, n/total (%)	239/271 (82%)	246/271 (90.8%)	133/154 (86.4%)	352/388 (90.7%)	53/53 (100%)	0.005
Procedure/device-related safety adverse event within 7 days	27/271 (10.0%)	15/271 (5.5%)	19/154 (12.3%)	23/288 (5.8%)	0/53 (0.0%)	0.01
Serious pericardial effusion within 7 days	17/271 (6.3%)	10/271 (3.7%)	10/154 (6.5%)	17/388 (4.4%)	0/53 (0.0%)	0.03
Procedure time, mean ± SD, min	67 ± 36	58 ± 33	82 ± 40	55 ± 29	48 ± 11 (mean time for first 3 patients)	0.23 (first 3 patients, head-to-head comparison)

CSHD = Center for Structural Heart Disease, Henry Ford Health System; other abbreviations as in Table 3.

the safety and reduce the challenges seen in the early learning experience of WATCHMAN implantations. It should be noted that a 16.3% rate of serious pericardial effusions and procedure- or device-related safety adverse events were attributed to the early operator learning curve witnessed in the PROTECT AF study (5). Three-dimensional CT guided case planning for the LAA is not only more accurate but provides faster, safer, and personalized care to patients than allowed by fluoroscopy or TEE imaging alone.

STUDY LIMITATIONS. We report a single-center experience with a small sample size. There is an important learning curve to CT-guided identification of the LAA landing zone for WATCHMAN implantation and associated catheter depth positioning for case plan generation. Prospective studies using 3D CT imaging for sizing and procedural planning will be needed to prove superiority in performance to standard 2D TEE guidance.

With our CT case planning, each patient had a 3D printout generated that included the left atrium and LAA anatomy. The early CT case planning was adapted from bench modeling testing of WATCHMAN devices in the 3D printout and then applied to the CT post-processing to understand the definition of the LAA landing zone and positioning necessary for successful WATCHMAN implantation. The incremental value of 3D printing added to the LAA device case planning served as a safety net in procedural planning awareness that is difficult to quantify.

CONCLUSIONS

Accurate sizing and deployment of the WATCHMAN device is achievable in a safe and precise environment with the incorporation of advanced 3D CT case planning. Detailed understanding and analysis of the size of the landing zone, angulation of the LAA main lobe, and location of trabeculations and pectinate muscle is necessary for successful device implantation. Our study is distinguished by reporting not only the differences in imaging modalities but the impact of their implementation on clinical success. Comprehensive CT case planning is not only feasible but may enhance procedural safety and efficiency, analogous to the impact delivered in transcatheter aortic valve interventions.

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PERSPECTIVES

WHAT IS KNOWN? Two-dimensional TEE imaging is currently the gold standard and recommended imaging modality for LAA occlusion with the WATCHMAN device.

WHAT IS NEW? Application of 3D CT imaging allows a comprehensive analysis of LAA anatomy and more appropriate device size selection and requires fewer devices per case. Application of 3D CT image guidance in new implanting sites may reduce the duration of procedures and reduce complications.

WHAT IS NEXT? Prospective randomized clinical trials are necessary to prove that computed tomography is responsible for improved procedural and safety outcomes compared with traditional imaging modalities.

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