



# A Comparative Study of Three Imaging Modalities for Size Selection of a Watchman Left Atrial Appendage Closure Device

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**Purpose:** To compare the results of computed tomography angiography (CTA), transesophageal echocardiography (TEE), and digital subtraction angiography (DSA) measurements and analyze their accuracy, correlation, and consistency in patients who have successfully undergone left atrial appendage closure (LAAC).

**Materials and Methods:** A total of 157 non-valvular atrial fibrillation (AF) patients who underwent LAAC with Watchman devices were included in the study. The maximum diameter and depth of LAA were recorded using CTA, TEE, and DSA. Correlations and agreements were compared.

**Results:** The LAAC procedure was performed successfully in all patients using the Watchman device. There was no significant difference between DSA and TEE measurements of the diameter of the LAA ostium. LAA ostium diameter obtained by CTA, however, was greater than that from DSA and TEE. Correlations were good between LAA ostium diameter measured by TEE, CTA, and DSA and Watchman device size. DSA measurements and actual device size showed the widest limits of agreement, followed by TEE; CTA measurements showed the narrowest limits of agreement. For LAA depth measurements, mean CTA measurements were higher than those of TEE and DSA. There was no significant difference in depth measurements among the three imaging modalities.

**Conclusion:** CTA, TEE, and DSA measurements exhibited good correlations with Watchman device size. The ostium diameter and depth of the LAA measured by CTA were greater than those measured by TEE and DSA. The relevance and concordance of CTA measurements were the strongest.

**Key Words:** Left atrial appendage closure, non-valvular atrial fibrillation, CT angiography, transesophageal echocardiography, digital subtraction angiography.

## INTRODUCTION

Non-valvular atrial fibrillation (AF) is the most common clinical arrhythmia, and AF-associated stroke is the condition's

most fatal complication.<sup>1</sup> The main source of thrombus in patients with AF at high risk of stroke is the left atrial appendage (LAA).<sup>2</sup> Due to the contraindications and disadvantages of anticoagulants, left atrial appendage closure (LAAC) has been shown to be an effective method for preventing stroke in AF patients at high stroke risk.<sup>3</sup> A key part of the procedure is fully evaluating the shape and depth of the LAA. To do so, it is essential to obtain optimal LAA imaging and sizing to improve the chances of a successful LAAC procedure. Undersizing of the occluder may result in large amounts of residual leakage around the device and even device-related thrombus (DRT) formation, whereas oversizing of the occluder carries the risk of cardiac tamponade.<sup>4</sup> Computed tomography angiography (CTA), transesophageal echocardiography (TEE) and intraoperative digital subtraction angiography (DSA) are usually used

**Received:** August 6, 2021 **Revised:** October 6, 2021

**Accepted:** November 30, 2021

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•The authors have no potential conflicts of interest to disclose.

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to assess LAA size and shape before LAAC. However, there are limited data comparing CTA, TEE, and DSA for diagnostic accuracy and practicality for LAAC. Therefore, we sought to compare the results of CTA, TEE, and DSA measurements and analyze their accuracy, correlation, and consistency in patients who have successfully undergone LAAC.

## MATERIALS AND METHODS

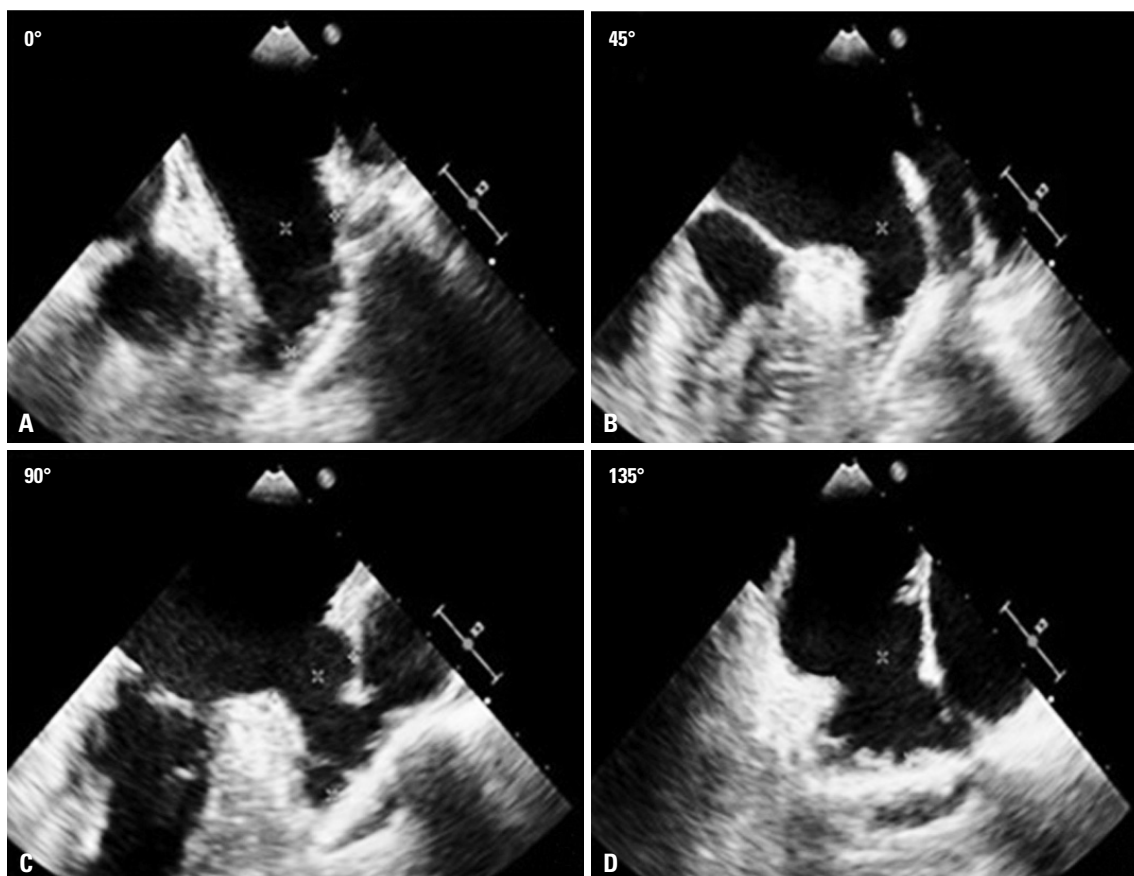
### Study population

A total of 157 consecutive patients with AF who underwent LAAC at Taizhou People's Hospital from March 2018 to November 2020 was included in the retrospective study. The diagnosis of AF was mainly based on the criteria listed in the 2016 ESC Guidelines for the management of AF developed in collaboration with EACTS.<sup>5</sup> Indications for LAAC were AF with high stroke risk (CHADS-VASc  $\geq 2$  in males or CHADS-VASc  $\geq 3$  in females) and contraindications to oral anticoagulants.<sup>6</sup> Baseline clinical characteristics were collected, including age, sex, CHA<sub>2</sub>DS<sub>2</sub>-VASc score, HAS-BLED score, comorbidities, medical history, left ventricular ejection fraction, perioperative adverse events, LAA measurements, and postoperative follow-up. This study was approved by the Ethics Committee of Jiangu

Taizhou People's Hospital, China (IRB No. KY202008001). Written informed consent for the procedure and data collection was obtained from all patients before inclusion for analysis.

### Pre-procedural protocols

To ensure standardized volume status for LAA sizing in the study, 500 mL of saline infusion were given to patients before TEE, CTA, and LAAC. TEE and CTA were performed 24 hours before LAAC to exclude the presence of thrombi in the left atrium (LA) or LAA and measure the data of the ostial dimensions and depths of LAA. TEE was performed using a Philips EPIQ 7C (Andover, MA, USA) ultrasound. LAA morphology, lobulation, and thrombi were observed from approximate TEE angles of 0°, 45°, 90°, and 135° in the LA at the end of the systolic period. The maximum orifice diameter and depth of LAA were measured (Fig. 1). CTA was performed using a 128-slice dual-source computed tomography scanner (SOMATOM Force, Siemens, Germany). LA and LAA were reconstructed at the greatest dimension at 250 ms after the R wave. The maximum LAA ostium diameter and depth were measured by adjusting the orthogonal plane to create a cross-sectional image of the LAA ostium on the oblique coronal images, using the medial side of the left superior pulmonary vein ridge and the left circumflex branch as the segmentation basis (Fig. 2).



**Fig. 1.** Orifice diameter and depth of the LAA opening measured at TEE angles of (A) 0°, (B) 45°, (C) 90°, and (D) 135°. LAA, left atrial appendage; TEE, transesophageal echocardiography.



**Fig. 2.** Preoperative computed tomography angiography measurements of the diameter and depth of the LAA ostium. (A) Image of the LAA ostium in oblique coronal view. (B) Orthogonal view of (A). (C) Cross-sectional view of (A). LAA, left atrial appendage.

### Procedural protocols

The patients fasted for 6 hours before the operation. All operations were performed under deep intravenous anesthesia or general anesthesia and TEE monitoring. TEE was performed as described previously. The best position was selected according to reconstructed CTA images, and the best image was selected in the right anterior oblique (RAO) 0°–40° and caudal (CAU) 0°–40°, usually at angles of 30° (RAO) and 20° (CAU). Then, the maximum diameter and the depth were measured by DSA (Fig. 3). According to the measured diameter, depth, and shape of LAA under CTA, DSA and TEE, a 4–6 mm upsizing device above the largest diameter was chosen to ensure stable positioning and proper compression. A long sheath of 14 F was sent into the LAA. Subsequently, the Watchman device was carefully delivered into the LAA through the access system and released at the ostium of the LAA. Before release, the PASS principle was assessed by the device's position. Stable anchoring was confirmed by a tug test, an appropriate compression ratio (10%–25% of the device's original size), and complete sealing (residual flow  $\leq 3$  mm).<sup>7</sup> Once released, TEE and LA angiography were performed to reconfirm device implantation and evaluate complications, such as pericardial effusion. Technical success was defined as successful deployment according to the PASS principle.

### Post-procedure

Patients were treated primarily with anticoagulants (warfarin, dabigatran, or rivaroxaban) and aspirin or clopidogrel for 3 months, followed by aspirin and clopidogrel for another 3 months and then aspirin or clopidogrel indefinitely. Clinical follow-up was performed in a 1, 3, 6, and 12 months after surgery, then annually thereafter. CTA and TEE were reexamined at 3 months after LAAC to evaluate device positioning, residual leakage, DRT, endothelialization of the occluder and other complications.

### Statistical analysis

Statistical software SPSS 26.0 (IBM Corp., Armonk, NY, USA)



**Fig. 3.** Intraoperative digital subtraction angiography to measure the diameter and depth of the orifice of the left atrial appendage at the angle of right anterior oblique at 30° and caudal at 20°.

was used for analysis. The Kolmogorov-Smirnov test was employed to test whether the data were distributed normally. The continuous data in normal distribution are expressed as a mean $\pm$ standard deviation, and the continuous data in non-normal distribution are expressed as a median $\pm$ interquartile range. Three radiographic measurements were compared using a t-test. We measured correlation between CTA, TEE, and DSA measurements of LAA ostium diameter and depth using Spearman analysis. Agreement was achieved by regression of the deviation and mean of the two measurements of the same sample using a Bland-Altman plot (drawn by MedCalc 19.3.1 software), and the limit of agreement (limits of agreement) was plotted as an indicator of agreement. A *p* value of  $<0.05$  was used as the basis for determining statistical significance.

## RESULTS

### Baseline characteristics

A total of 157 patients who underwent LAAC with a Watchman device from March 2018 to November 2020 in Taizhou People's Hospital, Jiangsu was enrolled in the study. All patients had contraindications to long-term oral anticoagulant therapy. The median age was 67 years. Persistent and permanent AF was present in 114 patients (72.6%), whereas 38 (24.2%) had a history of stroke/transient ischemic attack. The mean CHA<sub>2</sub>DS<sub>2</sub>-VASc score was 4 (3–6), and the mean HAS-BLED score was 3 (2–5). The baseline demographics, clinical parameters, and morphologies of the LAA are detailed in Table 1.

**Table 1.** Baseline Characteristics

Characteristics	Value (n=157)
Age, yr	67 (57–83)
Male	91 (57.6)
Hypertension	104 (66.2)
Diabetes mellitus	31 (19.7)
Coronary artery disease	46 (29.3)
Congestive heart failure	35 (22.3)
Previous history of ischemic stroke/transient ischemic attack	38 (24.2)
Previous hemorrhagic stroke	5 (3.2)
Peripheral vascular disease	17 (10.9)
Atrial fibrillation type	
Paroxysmal	43 (27.4)
Persistent/permanent	114 (72.6)
Chronic kidney disease	44 (28.0)
Prior bleeding	21 (13.4)
Left ventricular ejection fraction, %	56 (32–68)
Pacemaker	12 (7.6)
Anticoagulation	
Warfarin	24 (15.3)
Dabigatran	106 (67.5)
Rivaroxaban	27 (17.2)
Labile INR	12 (7.6)
CHA <sub>2</sub> DS <sub>2</sub> -VASc, median (IQR)	4 (3–6)
HAS-BLED, median (IQR)	3 (2–5)
Lobes of LAA	
1 lobe	40 (25.5)
2 lobes	81 (51.6)
3 lobes	29 (18.5)
More than 3 lobes	7 (4.4)
Morphology	
Cauliflower	102 (64.3)
Chicken wing	26 (16.6)
Cactus	23 (14.6)
Wind stock	6 (3.8)

INR, international normalized ratio; LAA, left atrial appendage. Data are presented as n (%) or median (range).

### LAAC procedures and parameter analysis

The procedural details are listed in Table 2. Deep intravenous anesthesia was used in 101 (63.7%) patients and general anesthesia in 56 (36.3%) cases. All procedures were performed under TEE guidance. Primary technical success of LAAC was achieved in all cases with the Watchman device. The device was deployed at the first attempt in 142 (90.4%) cases. After successful device release, mild leaks (<3 mm) were observed in 14 cases and moderate leaks (3–5 mm) in 4 cases. Perioperative adverse events occurred in 5 (3.2%) cases including 2 pericardial effusions (1.3%) and 3 vascular complications (1.9%). Pericardial effusion requiring pericardiocentesis occurred in 1 case.

### The ostium diameters of LAA measured by CTA, TEE, and DSA

There was no significant difference in the diameter measurements of the LAA ostium between DSA and TEE (22.9±3.7 mm vs. 22.5±3.6 mm,  $q=0.92$ ,  $p=0.16$ ). Meanwhile, the diameter of the LAA ostium obtained by CTA (24.6±3.7 mm) was greater

**Table 2.** Procedural Characteristics

Characteristics	Value (n=157)
Anesthesia type	
Deep intravenous anesthesia	101 (63.7)
General anesthesia	56 (36.3)
Size of Watchman device	
21 mm	11 (7.0)
24 mm	28 (17.8)
27 mm	49 (31.2)
30 mm	30 (19.1)
33 mm	39 (24.8)
Compression ratio	
0°	21.6±2.7
45°	20.5±2.8
90°	17.6±2.3
135°	14.8±2.3
Number of devices per procedure	
1	142 (90.4)
2	13 (8.3)
3	2 (1.3)
Peri-device leak	
0 mm	139 (88.6)
0–3 mm	14 (8.9)
3–5 mm	4 (2.5)
>5 mm	0 (0)
Perioperative adverse event	
Pericardial effusions	2 (1.3)
Vascular complications	3 (1.9)
Pseudoaneurysm of femoral artery	1 (0.6)
Arteriovenous fistula	2 (1.3)

Data are presented as mean±standard deviation or n (%).

than that from DSA and TEE ( $q=3.92, p<0.01$ ;  $q=4.58, p<0.01$ , respectively).

For the measurements of the LAA ostium, there were reasonably good correlations among the three modalities, with  $r=0.78$  and  $p<0.001$  between TEE and CTA,  $r=0.85$  and  $p<0.01$  between TEE and DSA,  $r=0.77$  and  $p<0.001$  between CTA and DSA (Fig. 4A-C). There were also good correlations between the LAA ostium measured by TEE, CTA, and DSA and the Watchman device size, with  $r=0.85$  and  $p<0.01$ ,  $r=0.92$  and  $p<0.01$ ,  $r=0.79$  and  $p<0.01$ , respectively (Fig. 4D-F). Among these, the relevance of CTA measurements was the best.

A Bland-Altman diagram was used to analyze consistency. The results showed that the  $p$  values of CTA vs. DSA, CTA vs. TEE, and TEE vs. DSA were 0.0855, 0.0663, and 0.9916, respectively ( $p>0.05$ ). These results indicated that the difference and mean values were independent and that the consistency limit could be calculated. Compared with DSA, 6.25% (5/80) of CTA measurements were outside the consistency limit, and the maximum difference/mean value within the limit was 38.68% (8.8/22.75). Compared with TEE, 7.5% (6/80) of CTA measurements were outside the consistency limit, and the maximum difference/mean value within the limit was 35.6% (8.1/22.75). The error of comparison between CTA and TEE was beyond the clinically acceptable range ( $\pm 25\%$ ). Compared with DSA, 3.75% (3/80) of TEE measurements were outside the consistency limit, the maximum difference/mean value within

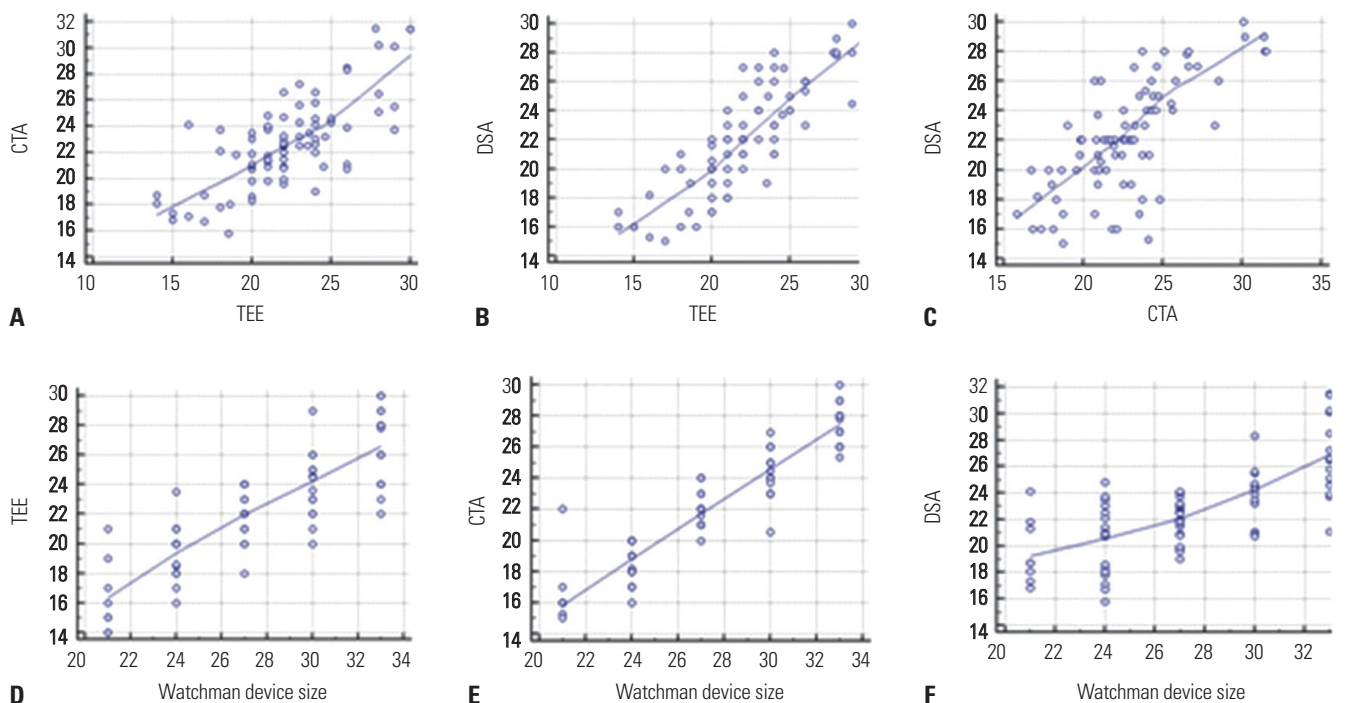
the limit was 22.52% (5/22.20). The error was within the clinical allowable range ( $\pm 25\%$ ) (Fig. 5A-C). Combined with correlation analysis, the correlation coefficient of TEE and DSA was  $r=0.86$ , indicating that the results measured by the two methods had good consistency and that the two methods can be used in place of each other in the clinic.

DSA measurements and actual device size showed the widest limits of agreement (-9.3120 mm, 0.2395 mm), followed by TEE (-9.4445 mm, -1.0205 mm), and CTA, which showed the narrowest limits of agreement (-8.7912 mm, -1.8724 mm). The  $p$  values of the regression analysis of DSA, TEE, and CTA with the occluder were 0.0003, 0.008, and 0.3102; the  $p$  values of TEE and DSA were statistically significant (Fig. 5D-F). These results suggested that CTA measurements were closer to the actual Watchman device size.

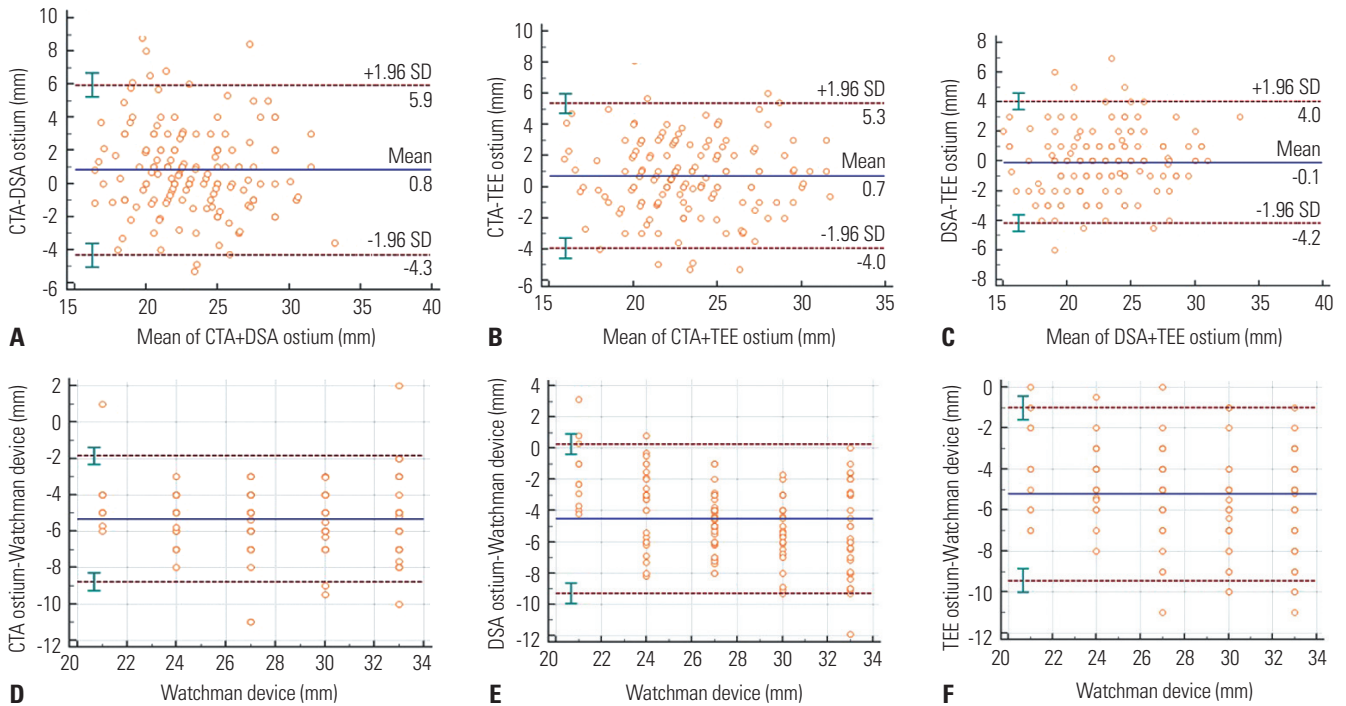
For LAA depth measurements, mean CTA measurements (25.1 $\pm$ 3.9 mm) were higher than those of TEE (24.6 $\pm$ 3.7 mm) and DSA (23.9 $\pm$ 3.6 mm). There were no significant differences in the depth measurement between CTA and DSA, CTA and TEE, TEE and DSA ( $p>0.05$ ). The correlations between TEE and CTA ( $r=0.6, p<0.01$ ), TEE and DSA ( $r=0.75, p<0.01$ ), CTA and DSA ( $r=0.59, p<0.01$ ) were positive and statistically significant (Fig. 6).

### Outcomes of follow-up at 3 months after LAAC

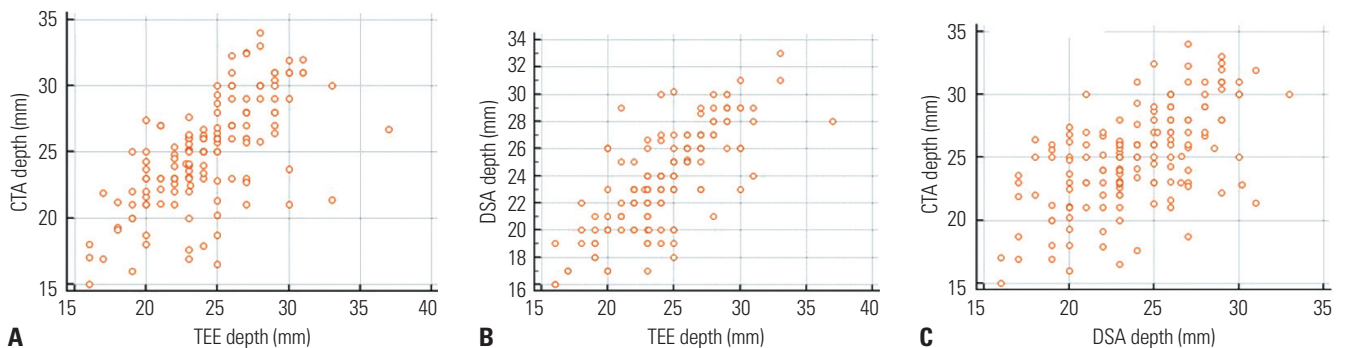
At 3 months after surgery, CTA and TEE were performed. The



**Fig. 4.** Correlation of LAA ostium measurements between the three modalities and correlation between the LAA ostium measured by three modalities and Watchman device size. (A) Scatter plot of TEE vs. CTA, (B) scatter plot of TEE vs. DSA, (C) scatter plot of CTA vs. DSA, (D) LAA ostium measured by TEE vs. Watchman device size, (E) LAA ostium measured by CTA vs. Watchman device size, and (F) LAA ostium measured by DSA vs. Watchman device size. CTA, computed tomography angiography; DSA, digital subtraction angiography; TEE, transesophageal echocardiography; LAA, left atrial appendage.



**Fig. 5.** Agreement of LAA ostium measurements between the three modalities analyzed by Bland-Altman diagrams: (A) Bland-Altman plot of CTA vs. DSA, (B) Bland-Altman plot of CTA vs. TTE, (C) Bland-Altman plot of DSA vs. TTE, (D) Bland-Altman plot of CTA vs. Watchman device, (E) Bland-Altman plot of DSA vs. Watchman device, and (F) Bland-Altman plot of TEE vs. Watchman device. CTA, computed tomography angiography; DSA, digital subtraction angiography; TEE, transesophageal echocardiography; LAA, left atrial appendage.



**Fig. 6.** Correlation of LAA depth measurements between the three modalities: (A) scatter plot of CTA vs. TEE, (B) scatter plot of DSA vs. TEE, and (C) scatter plot of CTA vs. DSA. CTA, computed tomography angiography; DSA, digital subtraction angiography; TEE, transesophageal echocardiography; LAA, left atrial appendage.

Watchman devices of all patients were in place. There were 129 (82.2%) patients without residual flow. DRT was noted in 7 (4.9%) patients at 3 months after the procedure. Corresponding therewith, 2 (1.3%) cases of stroke were recorded. Bleeding complication was observed in five cases at 3 months after operation, including one case of gastrointestinal hemorrhage, one case of hemoptysis, one case of urinary system hemorrhage, and two cases of skin ecchymosis. The results are listed in Table 3.

## DISCUSSION

Presently, CTA, TEE, and DSA are recommended for measur-

ing orifice diameter and depth of the LAA for selecting the appropriate size of a closure device. However, in this study, the three imaging modalities produced inconsistent results in regards to the diameter and depth of the LAA. Previous results have suggested that the LAA ostium size measured by CTA was larger than that found using TEE and DSA.<sup>8,9</sup> Reports by Chow, et al.<sup>10</sup> indicated that the narrowest limits of agreement were between device size and CTA measurements and that choosing the LAA occluder size based the CTA measurements was more accurate than conventional use of TEE. The results in this study highlighted positive correlations among the three imaging methods (CTA, TEE, and DSA). There were also good correlations between LAA ostium measured by TEE, CTA, and DSA and Watchman device size, which indicated that the three

**Table 3.** Follow-Up Outcomes at 3 Months

Variable	LAAC (n=157)
Occluder displace	0 (0.0)
Residual flow	
0 mm	129 (82.2)
<3 mm	24 (15.3)
3–5 mm	4 (2.5)
≥5 mm	0 (0.0)
Device-related thrombus	7 (4.9)
Stroke	2 (1.3)
Bleeding	5 (3.2)
Post-procedure medications	
Warfarin	24 (15.3)
Dabigatran	106 (67.5)
Rivaroxaban	27 (17.2)
Aspirin	126 (80.2)
Clopidogrel	31 (19.8)

LAAC, left atrial appendage closure.

modalities might provide valuable reference measurements for the selection of a Watchman closure device. We further compared the accuracy of different LAA imaging and sizing modalities and aimed to obtain optimal modalities for the selection of percutaneous LAA closure. Our results showed that the ostium diameter and depth of the LAA measured by CTA were greater than those measured by TEE and DSA. On the other hand, there was no significant difference in measurements of LAA ostium diameter between DSA and TEE. CTA measurements showed the narrowest limits of agreement with the Watchman device. The results were consistent with the reports of Saw, et al.<sup>8</sup> and Calkins, et al.<sup>11</sup> According to our results, among the three imaging modalities, the relevance and concordance of CTA measurements were the best.

CTA, a non-invasive modality with superior spatial resolution, arbitrary scans, and three-dimensional assessment, is increasingly performed for baseline imaging and post-LAAC imaging. TEE is an invasive method, and images are operator-dependent. TEE images for Watchman implantation are measured at four angles, namely, 0°, 45°, 90°, and 135°. Thus, even though TEE is a conventional modality recommended for LAA measurements and for selecting occluder devices, the maximal dimension and depth measured with TEE are perhaps inaccurate, which may lead to oversizing or undersizing. DSA is another valuable reference measurement for LAAC, in addition to CTA and TEE. However, multiple angiogram projections are not routinely performed to obtain the true maximal dimensions and depths of the LAA in all patients.

This study has a few limitations. First, it was conducted as a single-center, retrospective study with a small sample size and a potential for patient selection bias. The reliability of the data and results needs to be further substantiated by studies with a larger sample size. Secondly, for different forms of LAA, there may be errors in measurement. A further large sample size is

required to validate the conclusions of this study. Meanwhile, intracardiac echocardiography-guided LAAC has been increasingly used with good procedural outcomes, compared to TEE, and has been proposed as an ideal alternative to TEE.<sup>12</sup> Because of the relatively high cost of the ICE catheter, however, we did not include this procedure for analysis.

In conclusion, LAA morphology is variable, and it is important to rationally apply radiographic accurate measurements to select a closure device of appropriate size. In this study, sizes of the LAA measured by CTA, TEE, and DSA showed positive correlations with the size of the implanted occluder. The ostium diameter and depth of the LAA measured by CTA were greater than those measured by TEE and DSA. Among the three imaging modalities, the relevance and concordance of CTA measurements with device size were the best.

## ACKNOWLEDGEMENTS

The study was supported by Jiangsu Provincial Medical Innovation Team (Grant No. CXTDB2017015), Jiangsu Commission of Health, China (Grant No. H201665) and the Six Talent Foundation of Jiangsu Province, China (Grant No. WSN-20). The authors would like to thank Prof. Bo Zhang and Guiyong Yang for their professional assistance with CTA and TEE.

## AUTHOR CONTRIBUTIONS

**Conceptualization:** Zhong-bao Ruan and Li Zhu. **Data curation:** Fei Wang. **Formal analysis:** Zhong-bao Ruan. **Funding acquisition:** Zhong-bao Ruan and Li Zhu. **Investigation:** Fei Wang. **Methodology:** Zhong-bao Ruan, Ge-cai Chen, and Li Zhu. **Project administration:** Fei Wang. **Resources:** Zhong-bao Ruan and Li Zhu. **Software:** Fei Wang. **Supervision:** Li Zhu. **Validation:** Zhong-bao Ruan. **Visualization:** Ge-cai Chen. **Writing—original draft:** Zhong-bao Ruan. **Writing—review & editing:** Zhong-bao Ruan. **Approval of final manuscript:** all authors.

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