

# Role of real time-three dimensional transesophageal echocardiography in left atrial appendage closure with LACBES® devices

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Received June 10, 2018; Accepted November 22, 2018

DOI: 10.3892/etm.2018.7086

**Abstract.** Catheter-based left atrial appendage closure (LAAC) has recently become an innovative strategy for preventing embolic events in patients with nonvalvular atrial fibrillation (AF). There is limited information on optimal sizing for LAAC with the recently developed LACBES® device. The aim of the present study was to assess the role of real time-three dimensional transesophageal echocardiography (RT-3D TEE) for LACBES® device selection during LAAC. A total of 22 patients with nonvalvular AF and indications for LAAC were enrolled in the study. All patients underwent LAAC with LACBES® devices. TEE was performed in all patients 3 days prior to the procedure, during the procedure, and 3 months and 1 year following the procedure. Interatrial septal puncture, exchange of the sheath and release of the device were performed under the guidance of RT-3D TEE. The LAA ostium and landing zone dimensions measured by RT-3D TEE were better correlated with the device size used for occlusion ( $r=0.60$ ,  $P=0.003$ ) than those measured with two dimensional TEE or LAA contrast angiography. There were no clinically significant residual shunts, pericardial effusion or tamponade following occlusion. All patients had the device well-seated and presented no evidence of closure-associated complications during the follow-up. No cases of peri-procedural stroke or mortality were observed during a mean follow-up period of 12 months. In conclusion, RT-3D TEE is a reliable and effective imaging

modality to guide LAAC using LACBES® devices in patients with nonvalvular AF at high risk of cardioembolic events.

## Introduction

Atrial fibrillation (AF) is a type of arrhythmia commonly encountered in clinical practice. AF is associated with a 5-fold increase in the incidence of cardioembolic stroke and a 3-fold increased risk of mortality (1). Accumulating evidence has demonstrated that left atrial appendage (LAA) is a major site of cardiac thrombus in patients with AF (1). Catheter-based LAA closure (LAAC) has recently become an innovative strategy for preventing cardioembolic events in patients with nonvalvular AF. The WATCHMAN™ LAAC device and the AMPLATZER Cardiac Plug are the most widely used closure devices worldwide, particularly in USA and Europe (2). The method to guide the implantation of these two types of LAAC devices is well defined (2,3). As three dimensional (3D) imaging modalities are more reliable and accurate than two dimensional transesophageal echocardiography (2D TEE) for the assessment of the LAA orifice size and provide a full view of the LAA, real time (RT)-3D TEE currently represents the first-line approach during the procedure of LAAC (2,3).

The LACBES® occluder has been recently developed by Changhai Hospital and Shanghai PushMed (Shanghai, China) (4). As a novel LAA device, there are limited data on the method of optimal sizing for the LACBES® occluder. Therefore, the present study evaluated the effectiveness of RT-3D TEE in guiding the LACBES® device deployment in patients with nonvalvular AF. To the best of our knowledge, this is the first study to investigate the feasibility of RT-3D TEE to guide LAAC with the LACBES® device. The present study has demonstrated that RT-3D TEE is a feasible, effective and safe method to guide LACBES® device deployment and has demonstrated that this method is more accurate than 2D TEE or LAA contrast angiography for device sizing during LAAC.

## Patients and methods

**Study population.** The present clinical study complied with the Declaration of Helsinki and was approved by the Ethics

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**Key words:** atrial fibrillation, echocardiography, left atrial appendage closure

Review Board of Shanghai Ninth People's Hospital, Shanghai Jiaotong University School of Medicine (Shanghai, China; approval no. 2016-45-C12). Individual permission was obtained from all the participants using a standard informed consent procedure.

A total of 22 consecutive patients (9 males and 13 females; age,  $74 \pm 9.2$  years) with nonvalvular AF, CHA2DS2-VASC score (1) [which assigns points for congestive heart failure, hypertension, age  $\geq 75$  years (doubled), diabetes, stroke (doubled), vascular disease, age 65-74 years and sex (female)]  $\geq 2$  and contraindication to oral anticoagulants (OACs) who were admitted to the Department of Cardiology, Shanghai Ninth People's Hospital Affiliated to Shanghai Jiaotong University School of Medicine between April and December 2016 were prospectively enrolled in the present study. The CHA2DS2-VASC score is the most commonly used method to predict thromboembolic risk in AF (1). Patients with CHA2DS2-VASC score  $\geq 2$  are at high risk of stroke and are recommended to receive OAC treatment (1). The present study excluded patients with newly diagnosed AF, hyperthyroidism-related AF, post-coronary artery bypass grafting AF, significant valvular heart disease, acute coronary syndrome, myocardial infarction within 3 months, presence of LAA thrombus, New York Heart Association functional class IV heart failure (5) or left ventricular ejection fraction (LVEF)  $< 40\%$ , hepatic or renal failure (creatinine clearance,  $< 30$  ml/min), active infectious endocarditis, acute stroke or transient ischemic attack within 30 days, chronic inflammatory or neoplastic diseases. Patients undergoing urgent surgery and those with active peptic ulcers or disorders in blood coagulation were also excluded. The Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly ( $> 65$  years), Drugs/Alcohol Concomitantly score was used to predict the bleeding risk in AF patients taking anticoagulants (1).

**Transthoracic echocardiography (TTE).** All patients underwent a routine TTE exam using a Philips iE Elite ultrasound instrument (Philips Medical Systems, Inc., Bothell, WA, USA) equipped with an S5-1 probe. Standard echocardiographic views and measurement were obtained according to the recommendations of the American Society of Echocardiography (6).

**TEE.** All patients underwent TEE examinations 72 h prior to the procedure, during the procedure, and at 3 months and 1 year following the procedure. TEE was performed using a 3D matrix-array transesophageal X7-2t transducer (Philips Medical Systems, Inc.). The left atrium, interatrial septum and LAA were then evaluated. The levels of mitral regurgitation, pericardial effusion and left superior pulmonary venous flow were measured. Using the 2D TEE mode, measurement of LAA dimensions was obtained at the  $0^\circ$ ,  $45^\circ$ ,  $90^\circ$  and  $135^\circ$  planes. The largest dimension was considered as the final result of 2D TEE measurement. Once the LAA was clearly displayed at  $90^\circ$ , the 3D mode was switched on. 3D TEE imaging was subsequently performed acquiring the usual pyramidal data set large enough to include the entire LAA. The zoom mode was used to improve the visualization of the LAA. The internal

Table I. Baseline clinical characteristics.

Variable	Value
Age, years	$74 \pm 9.2$
Male, n (%)	9 (40.9)
BMI, kg/m <sup>2</sup>	$23.52 \pm 2.71$
Hypertension, n (%)	11 (50.0)
Diabetes mellitus, n (%)	7 (31.8)
Coronary heart disease, n (%)	16 (72.7)
Duration of AF $< 1$ year, n (%)	4 (18.2)
Duration of AF $> 1$ year, n (%)	18 (81.8)
Previous stroke, n (%)	10 (45.4)
History of radiofrequency ablation, n (%)	6 (27.3)
Use of OACs, n (%)	8 (36.4)
CHA2DS2-VASc	$3.7 \pm 1.2$
HAS-BLED	$3.9 \pm 0.9$
Prior bleeding, n (%)	8 (36.4)
Bleeding with OACs	4 (18.2)

Values are expressed as n (%) or the mean  $\pm$  standard deviation. BMI, body mass index; AF, atrial fibrillation; OACs, oral anticoagulants; CHA2DS2-VASC, congestive heart failure, hypertension, age  $\geq 75$  years (doubled), diabetes, stroke (doubled), vascular disease, age 65-74 years and sex (female); HAS-BLED, Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly ( $> 65$  years), Drugs/Alcohol Concomitantly.

area and maximum diameter of the LAA orifice were measured directly from the original 3D views, along a plane connecting the origin of the left circumflex artery to the roof of the LAA, below the ligament of Marshall. These measurements were assessed online using the iE Elite ultrasound machine (Philips Medical Systems, Inc.). The LAA depth (defined as the longest distance from the LAA orifice at the circumflex artery level to the tip of the LAA) was measured off-line from the long-axis views, using dedicated software (QLAB 9.1; Philips Medical Systems, Inc.).

**Contrast LAA angiography.** The diameters of the landing zone were measured by contrast angiography in the (right anterior oblique  $30^\circ/20^\circ$ ) cranial and caudal views. The largest diameter in the different views was defined as the final diameter of the landing zone.

**Implantation of the LAA closure device.** The LACBES® occluder is made of nitinol wire mesh and consists of two parts, an anchor cylinder and a sealing disc, which are filled with a polyester fiber membrane (4). The anchor cylinder is made of weaved nitinol wires with 9-12 integrated micro-barbs. It lands at the landing zone and deeply anchors to the LAA as a supporting structure for the whole occluder, with the sealing disc sealing the LAA orifice. The sealing disc is curved inwards and is 6 mm larger in diameter than the anchor cylinder. The device is available with anchor cylinder sizes from 16-34 mm (2-mm size increments) and requires 9-14 French sheaths. The selection of device was based on the morphological characteristics of the LAA measured by

Table II. Measurements by echo during left atrial appendage closure procedure and in the follow-up.

Measurement	Baseline	Immediately after the procedure	3 months after the procedure	1 year after the procedure
LA diameter, mm	41.86±4.69	41.45±5.27	41.91±4.99	42.14±4.75
LVEDD, mm	47.77±3.60	48.36±3.98	47.59±3.63	47.73±3.28
LVESD, mm	32.32±3.64	32.36±3.78	31.91±2.96	31.64±2.65
LVEF, (%)	61.45±4.62	61.64±4.23	62.14±2.45	62.72±2.97
LSPV peak systolic velocity, cm/sec	54.1±10.1	52.3±8.6	56.7±9.3	55.5±7.9
Pericardial effusion	NA	0 (0)	0 (0)	0 (0)
Device displacement	NA	0 (0)	0 (0)	0 (0)
Thrombi formed on device	NA	0 (0)	0 (0)	0 (0)
Residual shunt around device <3 mm	NA	1 (4.5)	1 (4.5)	1 (4.5)

Values are expressed as n (%) or the mean ± standard deviation. LA, left atrium; LVEF, left ventricular ejection fraction; LVEDD, left ventricular end-diastolic dimension; LVESD, left ventricular end-systolic dimension; LSPV, left superior pulmonary vein.

2D-TEE, 3D-TEE and contrast angiography. The puncture of the atrial septum was guided by RT-3D TEE. Upon deployment of the occluder, the device's position and stability were tested by contrast angiography and TEE.

*Follow-up.* Upon LAA closure, TTE was performed at months 1, 3, 6 and 12, whereas 3D TEE was performed at months 3 and 12. Device position, device-related thrombi, left superior pulmonary vein velocity and pericardial effusion were recorded. Primary endpoints, defined as the onset of stroke, and serious adverse events such as hemorrhage, were monitored.

*Statistical analysis.* Continuous variables were expressed as the mean ± standard deviation and were compared using unpaired Student's t-test. For comparisons of >2 groups, one-way analysis of variance with post-hoc Tukey's test was used. When data were not normally distributed, they were expressed as the median and range, and were analyzed with Mann-Whitney U non-parametric tests. More than two groups were compared using the non-parametric Kruskal-Wallis test. Categorical variables were expressed as percentages. Agreement analysis between the device's size and the landing zone's diameter obtained by RT-3D TEE, 2D TEE and angiography was evaluated with Bland-Altman plots. Multiple linear regression analyses were used in a stepwise mode to assess the correlation among 2D TEE, 3D TEE, LAA angiography and device's size. A 2-sided P<0.05 was considered to indicate a statistically significant difference. All analyses were performed using SPSS version 19.0 software (IBM Corp., Armonk, NY, USA).

## Results

*Baseline characteristics.* The baseline clinical characteristics of the study population are presented in Table I. All patients (n=22) had notably high CHA<sub>2</sub>DS<sub>2</sub>-VASC score, and a high proportion of patients had suffered a previous stroke (45.4%). A total of 14 patients were contradicted to OACs. A total of 8 patients took OACs at low doses, as 3 patients

had bleeding tendency on OACs at routine doses and 5 patients had a history of prior bleeding (including prior ulcer bleeding, hematuria due to kidney stone and prior bronchiectasis hemoptysis). These 8 patients were not candidates for long-term OACs and thus were enrolled for the LAAC procedures. All patients underwent successful LAA closure with the guidance of RT-3D TEE. The duration of the procedure and the number of occluder devices used were 77.92±21.96 min and 1.14±0.36, respectively. During the procedure, only 1 case of clinically acceptable residual shunt (2-mm residual shunt) was noticed, while 2 patients exhibited evidence of minor pericardial effusion, and no tamponade was observed. No stroke due to the operation or any other LAAC-related complications were observed. The flow velocity of left superior pulmonary vein and the intensity of mitral regurgitation remained unchanged upon LAAC (Table II).

*Follow-up.* During the follow-up at 3 months and 1 year, TTE and TEE were performed. No device displacement, device-related thrombi or pericardial effusion were observed. Only 1 patient had clinically acceptable peri-device leakage (2-mm residual shunt). All the trans-septum puncture spots were recovered 3 months following the procedure. LVEF, LA volume and left superior pulmonary vein velocity at the 3-months and 1-year follow-up were similar to the baseline levels (Table II). Additionally, no stroke, major bleeding or adverse outcomes were recorded (Table II).

*Comparisons among 2D TEE, RT-3D TEE, LAA contrast angiography and implanted device.* The whole procedure was performed under the guidance of 2D TEE and RT-3D TEE. The interatrial septal puncture, delivery of the sheath, release of the occluder device and peri-device leakage were monitored and evaluated by 2D and 3D TEE (Figs. 1 and 2). The diameter of the landing zone was measured by 2D TEE, 3D TEE and X-rays (Fig. 3). As presented in Table III, the diameters of the landing zone obtained by 2D TEE, 3D TEE and contrast angiography were 22.91±4.13, 24.41±3.48 and 23.64±3.79 mm, respectively. The 3D TEE-derived



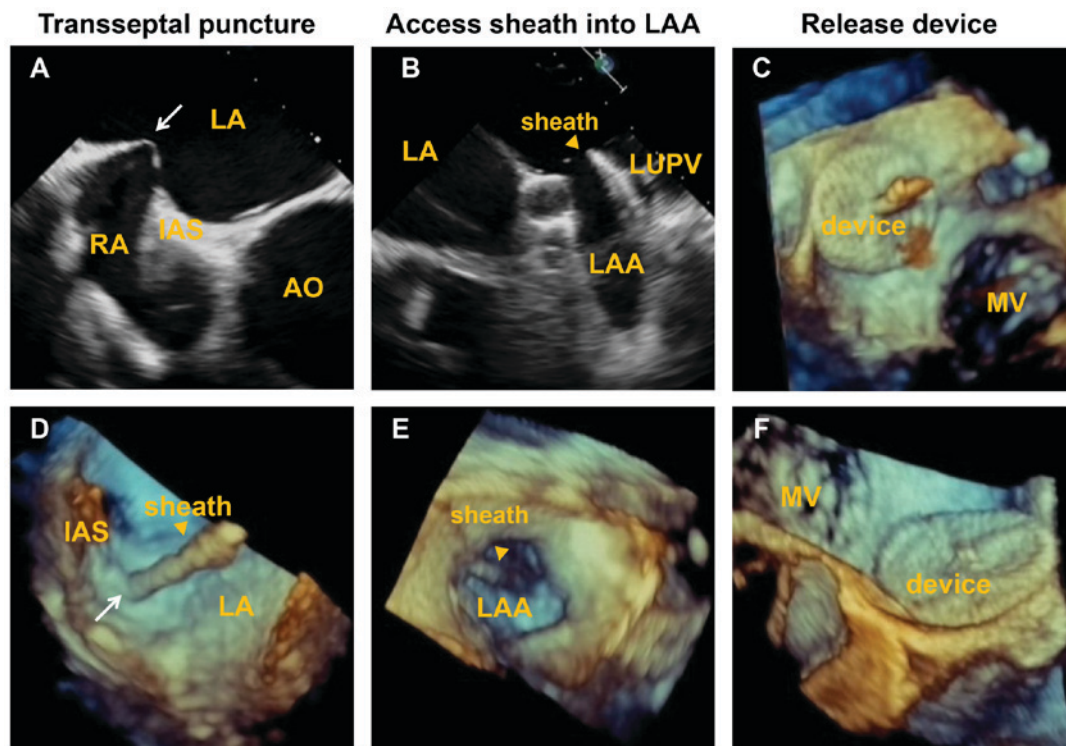


Figure 1. LAA closure procedures under the guidance of (A and B) two dimensional TEE and (C-F) real time-three dimensional TEE. (A and D) Representative images of interatrial septal puncture (arrow). (B and E) Representative images of the access of sheath into LAA. (C and F) Representative images of release of device. TEE, transesophageal echocardiography; AO, aorta; IAS, interatrial septum; LA, left atrium; LAA, left atrial appendage; MV, mitral valve; RA, right atrium.

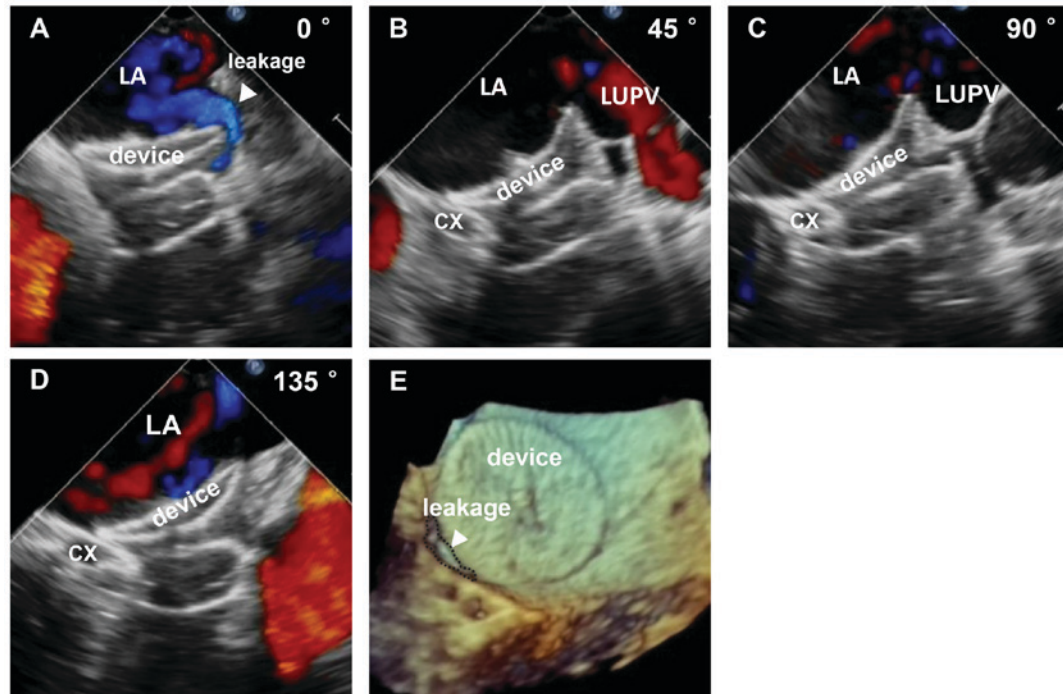


Figure 2. Images of peri-device leakage detected by (A-D) two dimensional TEE and (E) real time-three dimensional TEE. TEE, transesophageal echocardiography; LA, left atrium; CX, circumflex artery; LUPV, left upper pulmonary vein.

measurements were slightly larger than those obtained with 2D TEE and LAA contrast angiography. No statistically significant difference was observed among the parameters evaluated by these three methods.

*Correlation between different measurements and device size.* Multiple linear regression analysis was utilized to analyze the correlation between different measurements and device size. The results revealed that the diameter of the landing zone obtained

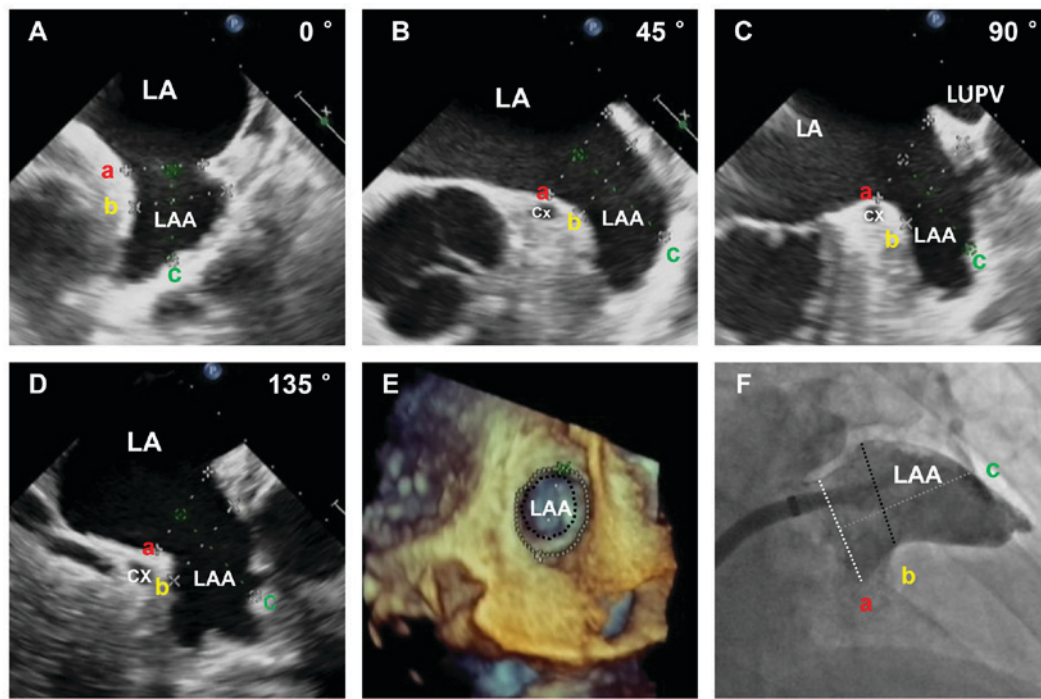


Figure 3. Measurements of the diameter of LAA landing zone by (A-D) two dimensional TEE, (E) real time-three dimensional TEE and (F) LAA angiography. Line a indicates the dimension of LAA ostium. Line b indicates the measurement of the landing zone. Line c indicates the LAA depth. TEE, transesophageal echocardiography; LAA, left atrial appendage; CX, circumflex artery; LA, left atrium.

by 3D TEE had a better association with the size of the implanted occluder than that obtained with 2D TEE and LAA angiography [3D TEE,  $r=0.60$ , 95% confidence interval (CI)=0.226-0.980,  $P=0.003$ ; 2D TEE,  $r=0.18$ , 95% CI=-0.044-0.405,  $P=0.11$ ; contrast angiography,  $r=0.24$ , 95% CI=-0.130-0.605,  $P=0.19$ ]. Bland-Altman analysis revealed positive correlation and low variability between the landing zone diameter measured by 3D TEE and the device's size (Fig. 4B). However, 2D TEE underestimated the diameter of the landing zone with marginal significance (Fig. 4A;  $P=0.062$ ).

## Discussion

The present study evaluated the feasibility and safety of RT-3D TEE to guide LAAC with the LACBES<sup>®</sup> device. Our main findings can be summarized as follows: i) Compared with conventional methods such as 2D-TEE and LAA contrast angiography, RT-3D TEE was more accurate in the decision of LACBES<sup>®</sup> device selection and guiding device deployment during the procedure; and ii) RT-3D TEE was a reliable and safe imaging modality for LAA occlusion in patients with AF, and was recommended for routine clinical application in LAAC with LACBES<sup>®</sup> devices.

The LACBES<sup>®</sup> device is a novel member of the LAA occluder family, which has recently been approved to be used in clinical trials in certain cardiovascular centers in China (4). It is composed of two parts, an anchor cylinder and a sealing disc (4). These two parts are connected by a long, thin waist. The anchor cylinder integrated with micro-barbs is harder than the sealing disc. Consequently, the anchor cylinder is able to land at the landing zone firmly, while the sealing disc is sufficiently flexible to cover the orifice seamlessly with minimal damage to the left atrial or LAA wall. As a novel device, there is little

information for determining the optimal size of the device and guiding the device deployment during the procedure.

In the present study, a total of 22 consecutive patients underwent LAAC with the LACBES<sup>®</sup> device between April and December 2016. As LAAC is an invasive procedure, the present study excluded patients with severe conditions for safety and ethical reasons. During the procedure, all patients were generally anesthetized, mechanically ventilated and guided by 3D-RT TEE. All the patients tolerated the procedure well and were resuscitated 2 h following the procedure. The present study demonstrated that RT-3D TEE was safe and more valuable for LAAC in clinical practice than the two conventional methods, 2D-TEE and LAA contrast angiography. This was primarily due to three advantages: i) The precise determination of the morphology of LAA as well as the size of the LAA orifice and the landing zone; ii) guiding the puncture of the atrial septum; and iii) evaluating the position of the device in the cavity of the atrial appendage.

It is well known that implanting a smaller sized device may cause peri-device leakage, while using a larger sized device may increase the risk of LAA perforation and cardiac tamponade during and following the procedure. Therefore, accurate measurement of LAA is important for the selection of the optimal LACBES<sup>®</sup> device. In 2D TEE, the dimensions of the LAA orifice and landing zone were measured at the 0°, 45°, 90° and 135° planes, and the maximum measurement was used for device sizing (7,8). However, 2D TEE was frequently not parallel to the ostial plane (9). Due to the complexity of LAA, 2D TEE is unlikely to provide the accurate dimension of the LAA. By contrast, RT-3D TEE provides more information about the anatomy of LAA. The 3D TEE iCrop and iSlice model is capable of displaying the anatomical structures of LAA from any angle, including LAA ostial pattern, lobes and internal anatomy

Table III. Implanted device size and measurements by different methods.

Variable	Value
Devices used	1.14±0.36
Occlusion success rate	22 (100)
Device size (anchor cylinder diameter), mm	25.18±3.74
RT-3D TEE	
Orifice diameter, mm	26.36±4.17 <sup>a</sup>
Landing zone diameter, mm	24.41±3.48
2D TEE	
Orifice diameter, mm	22.64±4.09
Landing zone diameter, mm	22.91±4.13
LAA contrast angiography	
Orifice diameter, mm	24.40±4.77
Landing zone diameter, mm	23.64±3.79

Values are expressed as n (%) or the mean ± standard deviation.

<sup>a</sup>P<0.05 vs. 2D TEE. RT-3D TEE, real time-three dimensional transesophageal echocardiography; 2D TEE, two dimensional transesophageal echocardiography; LAA, left atrial appendage.

such as the tuberculations in each lobe. Therefore, it efficiently eradicates the measurement error and provides accurate information for device selection (10,11). As a result, the present study revealed that there was a stronger correlation between the dimension of the orifice and the landing zone measured by RT-3D TEE and the selection of closure device. However, device sizing parameters evaluated by 2D-TEE or LAA contrast angiography were slightly smaller than the size of the implanted device. Previously, Zhou *et al* (12) investigated the clinical value of 3D TEE in the periprocedure of LAA closure using LeFort or LAmbré devices, both of which are locally developed devices and available in China. In accordance with the present findings, the landing zone measured by RT-3D TEE Flexi Slice mode was strongly correlated with the size of the closure device. Furthermore, all patients in the present study underwent LAA closure under the guidance of RT-3D TEE. No cases of adverse events, such as device displacement, peri-device leakage, pericardial effusion or thrombus, were recorded immediately following the procedure, or at 3 or 12 months post-procedure. Only 1 case of clinically acceptable peri-device leakage (2-mm residual shunt) was observed.

Furthermore, atrial septal puncture is the crucial step for the LAAC procedure. Appropriate atrial septal puncture guarantees the sheath and the device to arrive at the LAA through the puncture point and to remain in a suitable orientation in the long axis of LAA (11). Co-axiality is also critical to adjust the device's angle and direction. Previous studies have demonstrated that a full view of the atrial septum can be easily obtained by RT-3D TEE, which facilitates the determination of the optimal puncture site (10,12,13). With the guidance of RT-3D TEE, no inappropriate puncture, puncture-related complications or undesirable co-axiality occurred in the present study. As a result, no deformation of closure devices or obvious residual leakage was observed during follow-up.

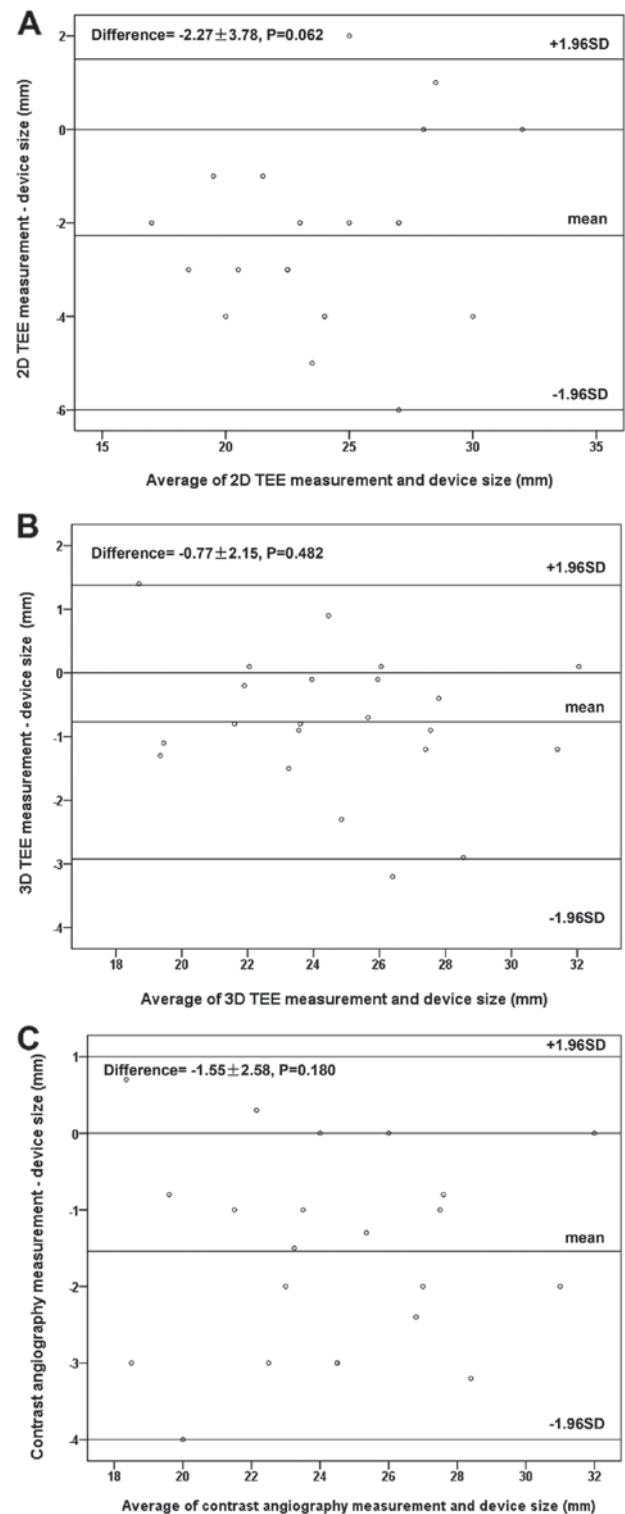


Figure 4. Scatter plots of Bland-Altman analysis of the difference between the size of implanted devices and the LAA landing zone diameter measured by (A) two dimensional TEE, (B) real time-three dimensional TEE and (C) LAA contrast angiography. TEE, transesophageal echocardiography; LAA, left atrial appendage.

In addition, RT-3D TEE provided the en face view of the closure device upon placement as well as the position of the device in LAA and the location between the adjacent structures. 3D TEE also displayed the comprehensive position of the device with respect to the dynamic movement of the mitral valve and the left superior pulmonary vein.



The present study presented several limitations. First, this is an observational study with a small number of patients in a single center. A larger scale multicenter study is desirable. Secondly, although RT-3D TEE is a more reliable and effective imaging method to guide LAAC than 2D TEE, 3D TEE is prone to artifacts from arrhythmia and ventilation (11,12). Particular attention should be paid to acquire 3D images and avoid motion artifacts during the procedure when patients are generally anesthetized and ventilated. Thirdly, 3D TEE can only be applied in experienced centers, as reconstruction of high-quality 3D images requires proficient skills and is time consuming. Lastly, in the present study, the closure device selection was predominantly based on RT-3D TEE, by which the largest size of the landing zone was obtained. Thus, it could cause a selection bias when evaluating the potential value of 2D TEE, 3D TEE and LAA angiography in LAAC device selection. The application of various novel 3D imaging techniques is likely to minimize the selection bias. Our future studies will investigate the significance of computed tomography-based 3D LAA models together with RT-3D TEE in LAAC procedures.

In conclusion, both 2D TEE and 3D TEE are useful in LAAC during the peri-procedure and follow-up. However, RT-3D TEE imaging is a more effective and accurate tool for improving the quality and safety of LAAC than conventional 2D TEE. It allows proper evaluation of the LAA's morphology, determination of the appropriate size of the device, continuous visualization of the catheter and device implantation, and precise delineation of the position of the device in LAA. All these aspects contribute to the intra-operative monitoring and evaluation of the closure in an accurate manner.

## Acknowledgements

Not applicable.

## Funding

The present study was supported by the National Natural Science Foundation of China grant (grant no. 81570037), the Key Basic Research Program of Shanghai Science and Technology Committee (grant no. 14JC14044) and the Shanghai Ninth People's Hospital MDT Program (grant no. 2017-1-015).

## Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## Authors' contributions

HZ designed the study, analyzed and interpreted the data, and drafted the manuscript. ZT performed the some of the trans-thoracic echocardiography (TTE) and the transesophageal echocardiography (TEE) examinations, analyzed the TTE/TEE data and made substantial contributions to the interpretation of the data. ZH performed the left atrial appendage closure procedures. LZ performed some of the TTE examinations. CW gave advice on the study design, interpreted the statistical analysis and critically revised the manuscript. All authors read and approved the final manuscript.

## Ethics approval and consent to participate

The present study was approved by the Ethics Review Board of Shanghai Ninth People's Hospital, Shanghai Jiaotong University School of Medicine (approval no. 2016-45-C12). All patients provided written, informed consent.

## Patient consent for publication

Not applicable.

## Competing interests

The authors declare that they have no competing interests.

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