



Left atrial appendage orifice diameter measured with trans-esophageal echocardiography is independently related with peri-device leakage after Watchman device implantation

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Abstract

Percutaneous left atrial appendage closure (LAAC) has emerged as an alternative of stroke prevention in non-valvular atrial fibrillation (NVAF) patients. Peri-device leakage after LAAC is common. This retrospective, case–control study aimed to identify risk factors related with peri-device leakage after LAAC with Watchman devices. Patients who underwent Watchman devices implantation received trans-esophageal echocardiography (TEE) before, during and 45 days after procedure. Peri-device leakage was defined as a residual flow of any size detected with TEE. Patients with residual flows were compared with sex and age matched controls without leakage after implantation. Basic clinical characteristics, as well as LAA imaging characteristics were collected and compared. From 2014 to 2016, 125 consecutive patients were implanted with Watchman devices in our center. TEE at 45 days after implantation identified 53 patients with peri-device leakages (2.62 ± 1.55 mm), who were compared with 43 sex and age matched controls who also received the Watchman devices implantation and had no peri-device residual flow. The basic clinical characteristics, as well as LAA morphology were comparable between the two groups, while patients with leakages had larger LAA orifice, longer LAA body and larger LAA volume. Multivariate logistic regression analysis showed that LAA orifice size measured with TEE was the only independent risk factor predicting post-procedural leakage. The AUC of the receiver operating characteristic (ROC) curve was 0.70. Using the TEE orifice size cutoff value of 18.7 mm yielded a sensitivity of 0.92 (specificity 0.52), while the cutoff value of 23.1 mm yielded a high specificity of 0.91 (sensitivity 0.24). Minor peri-device leakage (< 5 mm) is common after LAAC with Watchman devices. LAA orifice diameter measured with TEE is the independent risk factor predicting peri-device leakage after the implantation.

Keywords Left atrial appendage closure · Watchman device · Residual flow · Incomplete closure · Left atrial appendage morphology

Introduction

Non-valvular Atrial fibrillation (NVAF) is a common type of cardiac arrhythmia, with a prevalence of around 3% in western populations 20 years or older [1–3]. Ischemic stroke is one of the severe complications of NVAF, which in turn

is related with 20–30% of the ischemic stroke [4]. The age-standardized prevalence of AF is 0.66% in male, and 0.63% in female in Chinese population [5], and the stroke rate is as high as 6% per year [6]. Stroke prevention is of the utmost importance in the management of AF.

Autopsy and surgical data have demonstrated that 90% of atrial thrombus originated from the left atrial appendage (LAA) in NVAF patients [7]. Percutaneous left atrial appendage closure (LAAC) has emerged as an alternative for oral anticoagulants (OACs) therapy among NVAF patients with contraindications for long-term OACs or high bleeding risk.

A cluster of LAAC devices are available in clinical practice, among which Watchman device is supported by most solid clinical evidences [8–10]. However, post-procedural flows around LAAC devices are common. According to one

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study, the rate was 40.9% at 45 days follow-up, 33.8% at 6 months follow-up, and 32.1% at 12 months follow-up [11]. Another study reported rates of 29.3% at 45 days follow-up, and 34.5% at 12 months follow-up [12]. Currently, the risk factors predicting peri-device residual flow after LAAC remain under investigation. Some suggested that the residual flow might be attributed to the minor device shifting caused by the mismatch between the round shape of LAAC devices and the usually oval shape of LAA orifices [11], which was not backed by solid data. We speculated that peri-device residual flow might be related with LAA anatomical characteristics, like orifice diameter or morphology. This retrospective study was designed to identify risk factors related with residual flow around Watchman devices after implantation.

Methods

Study population

This is a retrospective study and patients' archived data was analyzed anonymously. The authors had no access to information that could identify individual participants during or after data collection. From May 2014 to May 2016, 125 consecutive patients received LAAC with Watchman devices. The indications for LAAC operations were as follows: patients were over 18 years of age, presented with paroxysmal or persistent non-valvular AF, with CHA2DS2-VASc score ≥ 1 , plus one of the following situations: a high bleeding risk (HAS-BLED score ≥ 3), a contraindication or an unwillingness to long-term warfarin/NOACs, or having a stroke/TIA despite of regular anticoagulant therapy. Baseline

clinical characteristics like gender, age, hypertension, diabetes mellitus, coronary artery disease, cardiomyopathy, congenital heart disease, congestive heart failure, ischemic stroke/TIA history, CHA2DS2-VASc score, HAS-BLED score and body mass index (BMI) were recorded for every patient. Patients with peri-device residual flows were compared with controls matched with age and sex, who also received the Watchman devices implantation and had no peri-device residual flow.

LAA imaging and measurement

LA diameter and left ventricular ejection fraction (LVEF) were measured with trans-thoracic echocardiography (TTE). LAA orifice diameter and LAA length were measured with trans-esophageal echocardiography (TEE) from 0, 45, 90, 135 degree sections and were presented as the average measurements of the four sections (Fig. 1a). TEE was also performed during and 45 days after the procedure to detect peri-device leakage (Fig. 1b).

Retrospective gating scan was used to collect LAA angiography with siemens dual source CT. Philips reprocessing software of EBW V4.0 was used to construct LAA 3-dimensional models. The CTA LAA orifice diameter was measured on two dimensional planes during 30–40% of the RR interval. As shown in Fig. 2a–c, the LAA opening was measured from the section between the circumflex artery and LSPV (Fig. 2a). An orthogonal cross-section of this plane was obtained (Fig. 2b). The LAA opening size was defined as the orifice perimeter divided by $\pi(3.14159)$ (Fig. 2c). LAA orifice morphology was assessed on the cross section of 3-D reconstructed

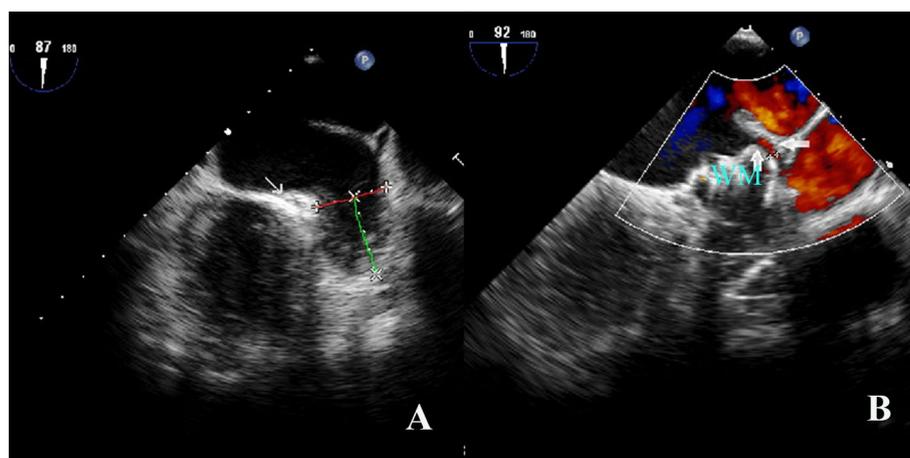


Fig. 1 TEE images of LAA measurement and peri-device residual flow. LAA orifice diameter and LAA length were measured with TEE from 0, 45, 90, 135 degree sections and were presented as the average measurements of the four sections. TEE was performed to assess the residual flow at 45 days follow-up. **a** TEE image of a patient whose

LAA orifice diameter (red line) and LAA length (green line) were measured at 90°. **b** TEE showed a peri-device flow of 3 mm (white arrow) at 45 days follow-up. TEE trans-esophageal echocardiography, LAA left atrial appendage, WM Watchman device

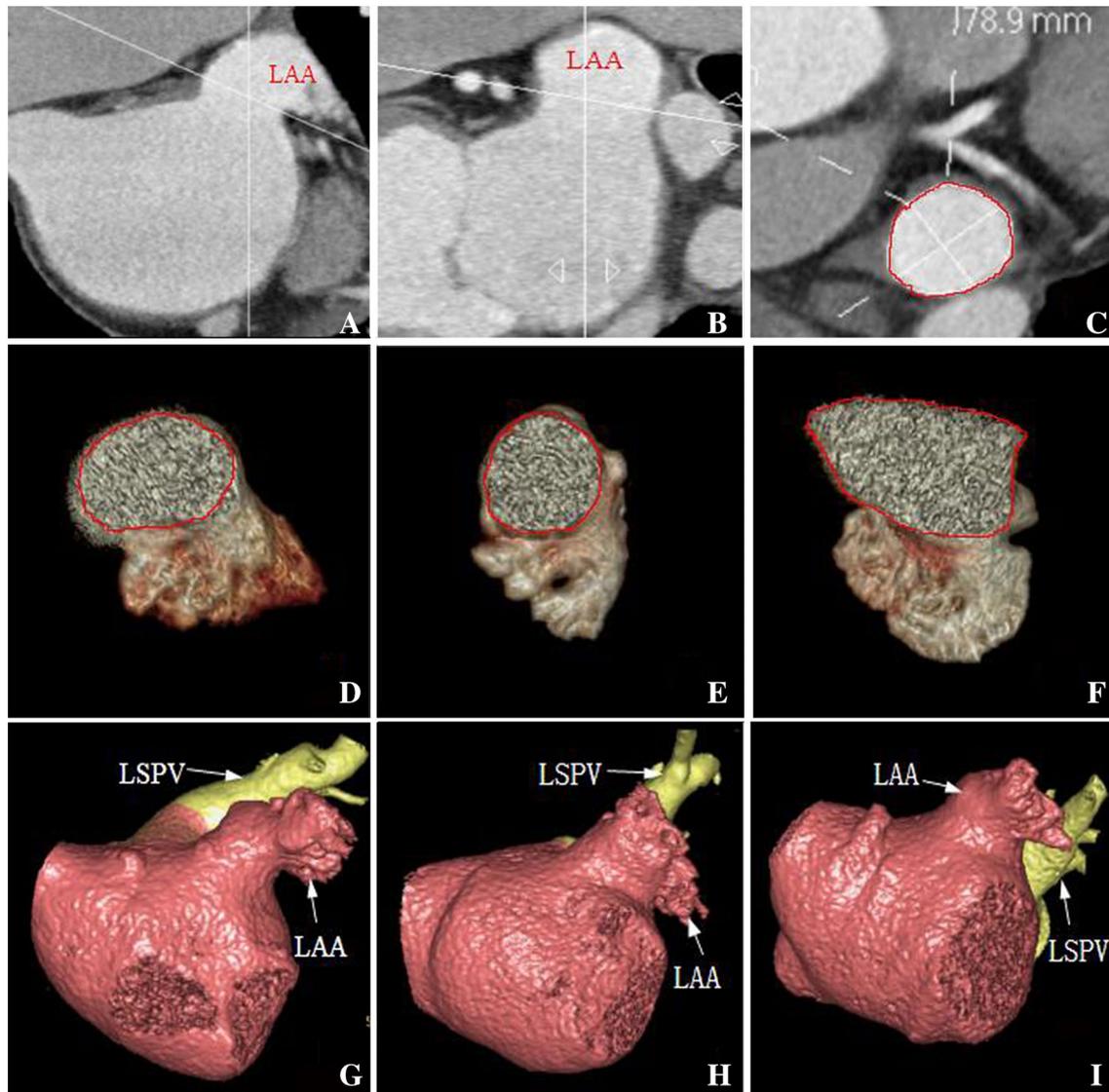


Fig. 2 CTA images of LAA orifice diameter measurement, LAA orifice morphology, and LAA position. Mean LAA orifice diameter was measured in 2D plane. **a–c** CTA image illustrating the measurement of LAA orifice diameter. LAA orifice section perimeter (red line, **c**) was measured, and LAA orifice diameter was obtained from perimeter divided by $\pi(3.14159)$. LAA orifice morphology and LAA

position were measured in 3D reconstructed models. **d** Oval orifice. **e** Round orifice. **f** Irregular orifice. **g** Low-position LAA (inferior to LSPV). **h** Middle-position LAA (parallel to LSPV). **i** High-position LAA (superior to LSPV). LAA left atrial appendage, LSPV left superior pulmonary vein. CTA computed tomography angiography

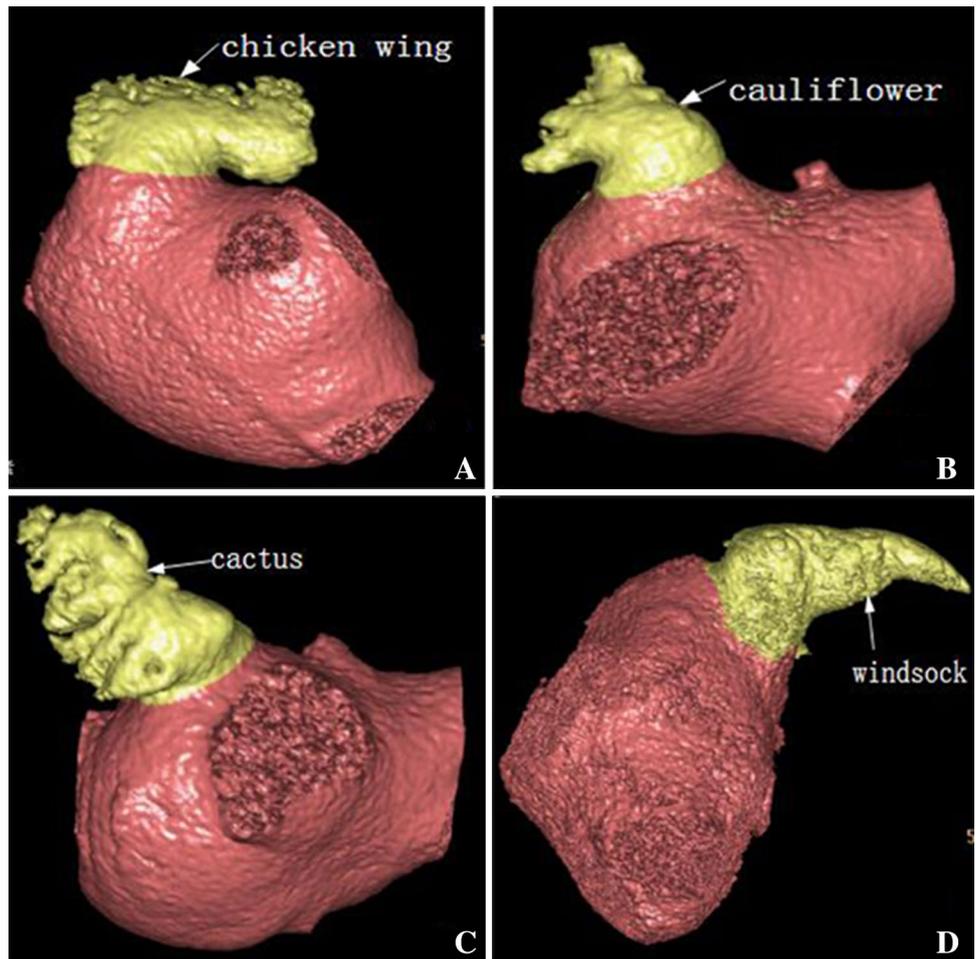
LAA models with LA removed (Fig. 2d–f). LAA position related to the left superior pulmonary vein (LSPV) was measured in 3D reconstructed models (Fig. 2g–i). LAA volume was determined by the LAA 3-D model.

The LAA morphology was classified into four types, namely, “cactus,” “cauliflower,” “chicken wing,” and “windsock” as defined by previous reports (Fig. 3).

Device implantation operations

Watchman devices were implanted through trans-septal approaches, using catheter-based delivery systems. Briefly, the operations were conducted under general anesthesia and tracheal intubation. After the TEE-guided atrial septum puncture, LAA angiography of the right

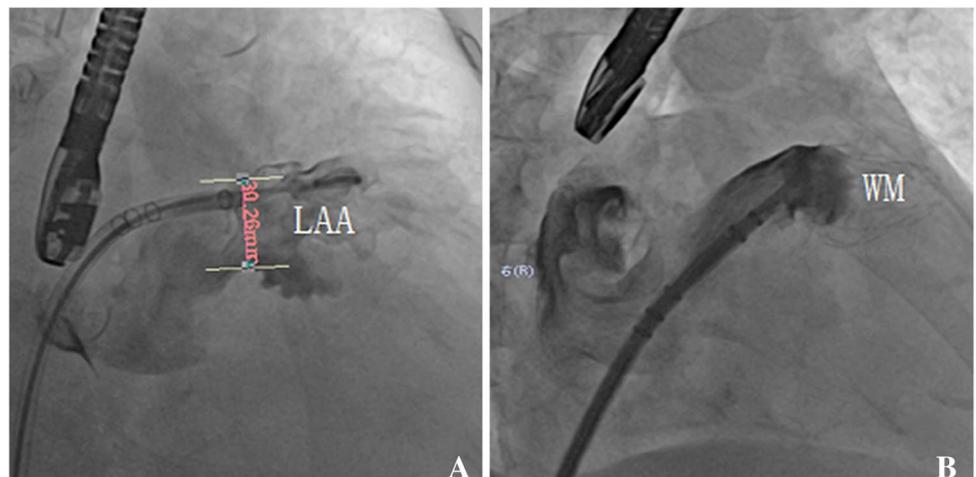
Fig. 3 LAA morphology. CTA images of some patients whose LAA morphology were showed in 3D reconstructed models: chicken wing (a), cauliflower (b), cactus (c) and windsock (d)



anterior oblique (RAO) at 30° plus caudal (CAU) at 20° was performed for LAA measurements. Watchman devices with suitable diameters (4–6 mm larger than LAA orifice diameter measured by the intraprocedural TEE) were delivered through a catheter-based delivery system and expanded to close the LAA openings (Fig. 4). During

the procedures, TEE was performed to confirm the LAA closure. Compression ratio of Watchman devices was calculated immediately after the procedures.

Fig. 4 Fluoroscopy images of LAA orifice diameter measurement and complete LAA closure with Watchman device. **a** An example of fluoroscopic LAA orifice diameter measurement before the device implantation. **b** Complete LAA closure shown with fluoroscopy after the device implantation



In-hospital management and follow-up

After the implantation procedures, patients were transferred to the cardiac care unit (CCU) for anesthesia recovery. A trans-thoracic echocardiography (TTE) was performed at the day of the operation to rule out cardiac effusion or device-related embolism. Then, 4 to 5 days of observation were completed before the patients discharged from hospital.

After devices implantation, patients received warfarin to maintain the INR ranging from 2.0 to 3.0. For some patients with warfarin contraindications, NOACs were prescribed. 45 days after the procedures, TEE was performed to assess the residual flow, stability of the device, and device-related thrombus-formation. If the TEE verified that LAAs had been closed with residual flows of less than 5 mm, warfarin was discontinued. Patients then took a combination of Aspirin and Clopidogrel for an additional 4.5 months. After that, patients received long-term Aspirin alone.

Statistical analysis

Data were presented with mean and standard deviation (SD) for continuous variables or with n and percentage for categorical variables. Comparisons were made with T test for normal distributed data. Mann Whitney U test was used for comparisons of non-normal distributed data. Categorical data were compared using χ^2 . Pearson correlation was applied to determine the correlations and consistencies of the data. Univariate and multivariate logistic regression analysis were performed to find independent risk factors related with residual flows. For risk factors found in multivariate logistic regression, a receiver operating characteristic (ROC) curve was drawn, and the area under the ROC curve and the best cut-off value were calculated. P values of less than 0.05 were considered significant. Statistical analyses were completed with SPSS v.16.0 statistical analysis software packet.

Results

From May 2014 to May 2016, 125 consecutive patients underwent Watchman devices implantation. All devices were successfully implanted except two with major leakages. 39 had acute leakages during operation (2.35 ± 2.01 mm). Only two had acute leakages larger than 5 mm, one of which (8 mm) closed spontaneously at 45 days follow-up, while the other (11 mm) remained unchanged and the patient continued with warfarin. At 45 days follow-up, the rate of peri-device leakage went higher as the number of leakages rose to 53, with the average leak size remained stable (acute 2.35 ± 2.01 mm vs. sub-acute 2.62 ± 1.55 mm, $P > 0.05$). To identify risk

factors related with peri-device flow after LAAC procedures, patients who had residual flows at 45 days post-procedure were compared with 43 age and sex matched controls who had no residual flow at the same time point.

The clinical characteristics were comparable between the two groups. For patients with residual flows, they were dominantly persistent AF (100%), the average age was 65.7 ± 7.8 years, 27 (50.9%) were female, 38 (71.7%) had hypertension, and 27 (50.9%) had previous stroke/TIA, which were not significantly different from the controls. Also, the average CHA₂DS₂-VASc score of patients with leakages was comparable to that of the controls (3.3 ± 1.6 vs. 3.0 ± 1.4 , $P > 0.05$), so was the HAS-BLED score (1.8 ± 1.1 vs. 1.9 ± 1.0 , $P > 0.05$) (Table 1). Although the device size was larger in patients with residual flows (29.3 ± 3.1 vs. 27.8 ± 3.7 , $P = 0.033$), it could be explained by their larger LAA opening size (described in detail below), as the compression ratio was not different between the two groups ($24.5 \pm 7.5\%$ vs. $22.9 \pm 8.9\%$, $P = 0.350$).

Comparisons of LAA imaging characteristics

The LAA anatomy was evaluated with various imaging measurements, including cardiac CTA, TEE and fluoroscopy.

TEE showed that patients with residual flows had larger LAA orifice diameters compared with the controls (21.3 ± 2.7 mm vs. 18.9 ± 3.8 mm, $P = 0.005$). Their LAAs were also longer (33.8 ± 5.9 mm vs. 29.7 ± 5.9 mm, $P = 0.011$). The LAA orifice diameters were consistently larger in fluoroscopy (22.9 ± 3.5 mm vs. 20.9 ± 3.4 mm, $P = 0.008$) and CTA measurements (26.3 ± 4.3 mm vs. 24.4 ± 4.5 mm, $P = 0.046$). About the measurements of LAA orifices, CTA/fluoroscopy/TEE showed moderate consistency. The R value was 0.664 for fluoroscopy/CTA ($P < 0.001$), 0.449 for fluoroscopy/TEE ($P < 0.001$), and 0.514 for CTA/TEE ($P < 0.001$).

In CTA measurement, LAA volume was larger among patients with leakages (12 ± 5.4 ml vs. 9.9 ± 4.2 ml, $P = 0.039$). Contrary to our anticipation, neither LAA position (compared to left superior pulmonary vein (LSPV)) nor LAA orifice shape was different between the two groups. Most LAAs were lower in position than LSPV in both groups (81.1% vs. 81.4%, $P > 0.05$). The most common orifice shape for both groups was ellipse (62.3% vs. 62.8%, $P > 0.05$), while the round and irregular shape were comparatively rare. As for the LAA morphology, 22(41.5%) patients had cauliflower-type LAAs, which was comparable to 20(46.5%) of the controls ($P > 0.05$). None of the rates of chicken wing, cactus or windsock morphology was different between the two groups (Table 2).

Table 1 Baseline clinical characteristics

	Case (n=53)	Control (n=43)	P	OR (95% CI)
Age (years)	65.7±7.8	65.4±7.2	0.803	–
Female gender, n (%)	27 (50.9%)	17 (39.5%)	0.265	1.588 (0.703,3.587)
Hypertension, n (%)	38 (71.7%)	30 (69.8%)	0.836	1.098 (0.454,2.656)
Diabetes mellitus, n (%)	7 (13.2%)	9 (20.9%)	0.313	0.575 (0.195,1.697)
Ischemic stroke/TIA history, n (%)	27 (50.9%)	16 (37.2%)	0.178	1.752 (0.772,3.979)
Coronary artery disease, n (%)	14 (26.4%)	14 (32.6%)	0.510	0.744 (0.307,1.798)
Congenital heart disease, n (%)	2 (3.8%)	1 (2.3%)	1	1.647 (0.144,18.802)
Cardiomyopathy, n (%)	3 (5.7%)	4 (9.3%)	0.774	0.585 (0.124,2.768)
Congestive heart failure n (%)	11 (20.8%)	7 (16.3%)	0.576	1.347 (0.473,3.837)
CHA2DS2-VASc score	3.3±1.6	3.0±1.4	0.338	
1	9 (17%)	8 (18.6%)	–	–
2	7 (13.2%)	7 (16.3%)	–	–
3	16 (30.2%)	15 (34.9%)	–	–
4	7 (13.2%)	7 (16.3%)	–	–
5	9 (17%)	3 (7.0%)	–	–
6	4 (7.5%)	3 (7.0%)	–	–
7	1 (1.9%)	0	–	–
HASBLED score	1.8±1.1	1.9±1.0	0.331	
0	5 (9.4%)	4 (9.3%)	–	–
1	16 (30.2%)	9 (20.9%)	–	–
2	21 (39.6%)	17 (39.5%)	–	–
3	8 (15.1%)	12 (27.9%)	–	–
4	2 (3.8%)	1 (2.3%)	–	–
5	1 (1.9%)	0	–	–
BMI	27.3±3.4	26.4±3.6	0.218	–
LAD (mm)	49.6±5.1	49.4±5.2	0.872	–
LVEF (%)	51.9±5.1	51.9±5.7	0.692	–

BMI body mass index, *TIA* transient ischemic attack, *LAD* left atrial diameter, *LVEF* left ventricular ejection fraction

* $P < 0.05$; ** $P < 0.01$

Risk factors of residual flow

Univariate analysis showed LAA volumes, LAA lengths measured with TEE, and LAA orifice diameters (measured with CTA/TEE/fluoroscopy) were related with post-procedural residual flows. Pearson's correlation analysis showed that LAA volume was strongly related with LAA orifice size ($R = 0.71$, $P < 0.001$), so the LAA volume was not included in the multivariate logistic regression analysis. LAA orifice size and LAA length measured with TEE were included in the multivariate analysis, which revealed that LAA orifice size (TEE) was the only risk factor independently related with post-procedural residual flow ($B = -0.255$, $P = 0.005$, Correct Class = 73.3%).

The area under curve (AUC) of the receiver operating characteristic (ROC) curve was 0.70 (95% CI 0.55–0.84, $P = 0.011$) (Fig. 5). When the cut-off value was set on 18.7 mm, the sensitivity was 0.92 and the specificity was 0.52. For a cut-off value of 23.1 mm, the sensitivity was

0.24 and the specificity was 0.91. Our data suggested that the orifice size of LAA might be useful when predicting post-procedure residual flow.

Discussion

The main findings of this study are: (1) Minor residual flows (< 5 mm) after left atrial appendage closure (LAAC) with Watchman devices are common; (2) LAA orifice diameter is an independent risk factor predicting residual flow after Watchman device implantation.

There are several ways to close LAAs, including surgical LAA ligation, percutaneous LAAC implantation, and percutaneous LAA ligation. Residual flow is a common issue after LAAC operation. For the most-widely used Watchman devices, Juan F et al. reported that 40.9% patients had residual flows at 45 days follow-up, and 32% patients had peri-device flows at 12 months [11]. Residual

Table 2 Imaging characteristics of LAAs

	Case (n=53)	Control (n=43)	P
LAA orifice (mm)			
TEE (mm)	21.3±2.7	18.9±3.8	0.005**
Fluoroscopy (mm)	22.9±3.5	20.9±3.4	0.008**
CTA (mm)	26.3±4.3	24.4±4.5	0.046*
LAA length (mm)	33.8±5.9	29.7±5.9	0.011*
LAA volume (ml)	12.0±5.4	9.9±4.2	0.039*
LAA device diameter (mm)	29.3±3.1	27.8±3.7	0.033*
Compression ratio (%)	24.5±7.5	22.9±8.9	0.350
LAA orifice shape			0.999
Oval	33 (62.3%)	27 (62.8%)	–
Circular	10 (18.9%)	8 (18.6%)	–
Irregular	10 (18.9%)	8 (18.6%)	–
LAA morphology			0.482
Cauliflower	22 (41.5%)	20 (46.5%)	–
Windsock	9 (17%)	3 (7.0%)	–
Chicken wing	4 (7.5%)	5 (11.6%)	–
Cactus	18 (34%)	15 (34.9%)	–
LAA position (to LSPV)			0.688
Low	43 (81.1%)	35 (81.4%)	–
Middle	7 (13.2%)	4 (9.3%)	–
High	3 (5.7%)	4 (9.3%)	–

LAA left atrial appendage, CTA computed tomography angiography, LSPV left superior pulmonary vein, TEE trans-esophageal echocardiography

* $P < 0.05$; ** $P < 0.01$

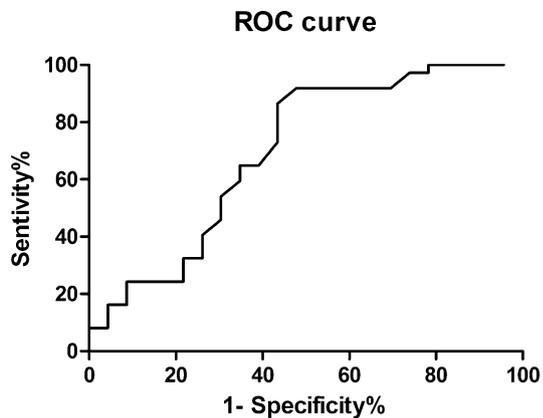


Fig. 5 Receiver operating characteristic (ROC) curve. The receiver operating characteristic (ROC) curve for the logistic model (LAA orifice diameter). The area under ROC curve is 0.70

flow is also a common issue for other LAAC devices [13–15]. For surgical LAA ligations, post-procedural residual flows were also common. Edward S reported that 36% of incomplete LAA closure occurred after surgical

LAA ligations [16]. In the study of Arash Aryana et.al, the rate was 24% after surgical LAA ligations [17].

Previous studies showed that the sizes of the residual flows of Watchman devices were mostly under 5 mm [11, 12], which was consistent with our study. The mechanism of incomplete closure after Watchman device implantation remains under investigation. Some researchers speculated that the shape of LAA orifice might be related with residual flow, namely the Watchman devices were round shape, which might be mismatching with oval or irregular shaped LAA orifices [11]. However, our data showed that this was not the case. The myocardium tissues around the LAA orifice were more distensible than LA and would adapt to the round shape of the devices [18]. Actually, we found that the LAA orifice after Watchman device implantation was round or near round, revealed by the TEE after the procedures (data not shown).

Another issue was the compression ratio. The manufacturer (Boston Scientific) recommended 8–20% compression ratio, but some recommended a higher compression ratio of 15–30% [19], which was consistent with our center. While high compression ratio could contribute to the device stability, it might hinder the full expansion of the devices, which could cause imperfect closures of LAAs. Chow et al. reported that 10–20% was a appropriate compression ratio for NVAF patients with WATCHMAN device implantation, and the lower or higher compression ratio might increase the risk of peri-device leakage [20]. And Phillips et al. also reported that the lower compression ratio might increase the risk of peri-device leakage [21]. However, the compression ratio of the Watchman device was found not to be related with residual flow in the study of Bai et al. [12], which was also consistent with our study. Further study is needed to clarify the relationship between compression ratio and residual flow.

LAA orifice size emerged as the only independent risk factor predicting postprocedural residual flow around the devices. Large LAA orifice diameter needs large Watchman device, which may be only partially endothelialized at postprocedural 45 days. Also, the large orifice may be relatively unstable with the closure devices. Compared with LA myocardium, LAA myocardium has a higher expansibility, so the discordance may lead to slight moving of the device from the LAA wall, which was more evident when the LAA openings were larger [18].

We used TEE, cardiac CTA, and angiography to evaluate LAA diameters, which were moderately consistent in their results. Each of the three measurements had its own unique characteristic. TEE was the most widely used method in the LAA assessment, which provided real-time LAA measurement during the procedure, when the LAA diameter might be influenced by LA pressures. Meanwhile, the measurements of LAA orifices, TEE showed moderate

consistency with the autopsy [22]. The LAA angiographic measurement was also useful because in our center, the majority of LAAC devices were implanted at the same fluoroscopic angle: right anterior oblique (RAO) 30° plus caudal (CAU) 20°. The angiographic measurement at this angle reassured the LAA size before the device implantation. The CTA provided detailed assessments of LAA anatomical features, like LAA opening shape, LAA position and LAA morphology. The CTA measurement of LAA orifice diameter was larger than TEE and cardiac fluoroscopy, which was consistent with previous reports [23]. Theoretically, CTA analysis might be the most accurate because it was easy to find the oblique plane where LAA opening sizes were largest. TEE or fluoroscopy measured LAA orifice diameters at set angles, which might be not the largest plane of LAA orifice size. On the other hand, CTA measurements were also limited by several factors. Firstly, CTA imaging could not be performed during the procedures, when LAA size could be influenced by LA pressures. Secondly, it was hard for CTA to distinguish between LAA thrombus formation and LAA columnae cordis. So we believe measurements of LAA with CTA/TEE/fluoroscopy were necessary for comprehensive assessments before LAAC procedures. The most widely used TEE, exhibiting consistency with other measurements, was used in our study for logistic regression and ROC analysis, and proved to be a predictor for post-procedural residual flow.

The clinical impacts of the residual flows have not been fully investigated. Studies reported varied results. There have been case reports indicating that residual flow was related with stroke or thrombi-formation [24, 25]. Bai et al. reported their single center experience that the rate of stroke among patients with residual flows was higher than those with no leakage [12]. However, other investigators reported that incomplete occlusions had no effect on the ischemic stroke or thrombi-formations [11]. So far, most data available are from non-randomized controlled trails with low stroke rates and short follow-up duration. It is interesting to mention that ischemic stroke rate was higher in LAAC patients [26] among whom leakage is common. Further study is needed to clarify the clinical impact of peri-device flow in LAAC patients.

Study limitations

This is a retrospective study, and the sample size is small. Besides, selection bias is obvious as our patients were all persistent AF with significantly enlarged LAs, which makes it impossible to know whether enlarged LA is a risk factor related with peri-device flow. Also, LAA enlarges significantly with markedly reduced contractility in persistent AF [27], which might cause instability and minor displacement

of the LAAC devices. The results should be taken with cautious as Further randomized trials were prompted to verify the findings and determine the clinical impact of peri-device residual flows.

Conclusion

This study indicates that LAA orifice diameter is independently related with residual flow after LAAC with Watchman device. This finding remains to be tested with prospective, multicenter and large sample trials.

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Compliance with ethical standards

Conflict of interest None of the authors have competing interests directly related to this work.

Informed consent The requirement for written informed consent was waived because this was a retrospective case-control study.

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