Changes In Left Atrial Appendage Orifice Following Percutaneous Left Atrial Appendage Closure Using Three-Dimensional Echocardiography

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Keywords: left atrial appendage occlusion, Watchman device, three-dimensional echocardiography, atrial fibrillation

Posted Date: July 13th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-662191/v1>

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Version of Record: A version of this preprint was published at Journal of the American College of Cardiology on March 1st, 2020. See the published version at [https://doi.org/10.1016/S0735-1097\(20\)32335-4](https://doi.org/10.1016/S0735-1097(20)32335-4).

Abstract

Purpose: Percutaneous left atrial appendage (LAA) occlusion is increasingly performed in patients with atrial fibrillation and long-term contraindications for anticoagulation. Our aim was to evaluate the effects of LAA occlusion with the Watchman device on the geometry of the LAA orifice and assess its impact on the adjacent left upper pulmonary vein (LUPV) hemodynamics.

Methods: We included 50 consecutive patients who underwent percutaneous LAA occlusion with the Watchman device. Three-dimensional images of LAA pre- and post-device placement were analyzed offline. We measured the LAA orifice diameters in the long axis, and the minimum and maximum diameters, circumference, and area in the short axis view. Eccentricity index was calculated as maximum/minimum diameter ratio. The LUPV peak S and D velocities pre- and post-procedure were also measured.

Results: Patients were elderly (mean age 76 ± 8 years), 30 (60%) were men. There was a significant increase of all LAA orifice dimensions following LAA occlusion: diameter 1 (pre-device 18.1 ± 3.2 vs. post-device 21.5 ± 3.4 mm, $p < 0.001$), diameter 2 (20.6 ± 3.9 vs. 22.1 ± 3.6 mm, $p < 0.001$), minimum diameter (17.6 ± 3.1 vs. 21.3 ± 3.4 mm, $p < 0.001$), maximum diameter (21.5 ± 3.9 vs. 22.4 ± 3.6 mm, $p = 0.022$), circumference (63.6 ± 10.7 vs. 69.6 ± 10.5 mm, $p < 0.001$), and area (3.1 ± 1.1 vs. 3.9 ± 1.2 cm², $p < 0.001$). Eccentricity index decreased after procedure (1.23 ± 0.16 vs. 1.06 ± 0.06 , $p < 0.001$). LUPV peak S and D velocities did not show a significant difference (0.29 ± 0.15 vs. 0.30 ± 0.14 cm/s, $p = 0.637$; and 0.47 ± 0.19 vs. 0.48 ± 0.20 cm/s, $p = 0.549$; respectively).

Conclusion: LAA orifice stretches significantly and it becomes more circular following LAA occlusion without causing a significant impact on the LUPV hemodynamics.

Introduction

The left atrial appendage (LAA) is the most common source of thrombi in patients with non-valvular AF, accounting for approximately 90% of cases.(1) Based on current guidelines, percutaneous LAA occlusion can be considered in selected patients with non-valvular AF who are at increased risk of stroke and have contraindications to long-term anticoagulation.(2) Based on recent randomized clinical trials that have demonstrated procedural safety and efficacy for ischemic stroke prevention with percutaneous LAA occlusion (3, 4), the US Food and Drug Administration has approved the Watchman device (Boston Scientific, Maple Grove, Minnesota) for use in percutaneous LAA occlusion. The Watchman is the only device specifically approved for LAA occlusion in the United States and has been increasingly utilized in real-world clinical practice(5).

The impact of the Watchman device on the LAA orifice and adjacent structures such as the left upper pulmonary vein (LUPV) is not well studied except in an animal model.(6). Potential damage to left pulmonary veins and the circumflex coronary artery is possible(7), these complications have been described mainly due to the Amplatzer cardiac plug device(8, 9). Accurate assessment of anatomic LAA

characteristics is crucial for correct sizing and safe placement of LAA closure devices.(10) Transesophageal echocardiography (TEE) is recommended before and during Watchman implantation to measure the LAA size(11). The depth and orifice diameters of the LAA are usually measured using two-dimensional (2D) TEE, however it has been shown that three-dimensional (3D) TEE is more accurate than 2D TEE and provides measurements that correlate better with those obtained by computed tomography. (12–15) The aim of this study was to evaluate the effects of LAA occlusion with the Watchman device on the geometry of LAA orifice using 3D TEE and assess its impact on the adjacent LUPV hemodynamics.

Methods

Study population

This was a retrospective observational study. A total of 64 patients with non-valvular AF underwent percutaneous LAA occlusion with the Watchman device between March 2019 to December 2019 at Yale-New Haven Hospital. Of these, we included 52 patients with 3D acquisitions of the LAA. Two patients whose quality of 3D images was suboptimal for analysis were excluded. Our final study cohort included 50 patients. Patients' clinical characteristics were obtained from electronic medical records. The study was approved by the Yale University Institutional Review Board.

LAA occlusion procedure

All implantation procedures were performed under TEE guidance. The size of the Watchman device implanted was determined by the maximum LAA ostium and depth measurements assessed by 2D TEE according to the recommendations by the manufacturer. TEE was used to assess the correct device position, ensuring a compression of 8–20% of its original size before release.

Transesophageal Echocardiography

Periprocedural 3D TEE was performed immediately before and after Watchman placement using the Acuson SC2000 machine equipped with the Z6MS transducer (Siemens Medical Solutions USA, Inc, Mountain View, CA) (Fig. 1). TEE was performed according to a standard protocol that includes the 2D assessment of the LAA in the mid-esophageal views at 0°, 45°, 90°, and 135°. LUPV flow was assessed using color and pulse-wave Doppler. Bidimensional and color doppler echocardiography was used to assess the presence and size of peri-device leaks. Three-dimensional TEE images of the LAA were obtained using a single beat acquisition with a volume size large enough to include the entire LAA (Fig. 1A and 1B). The 3D data sets were digitally stored for offline analysis. The LUPV peak systolic (S) and diastolic (D) velocities were measured offline in the echolab workstation.

Three-dimensional echocardiography analysis

3D images of LAA pre- and post-device placement were analyzed using the multiplanar reconstruction mode of TomTec Image-Arena, 4D Cardio-View Software (TomTec Imaging Systems GmbH, Unterschleissheim, Germany). As shown in Fig. 2, the left circumflex coronary artery (Cx) and the

Coumadin ridge were used as landmarks to ensure that the LAA ostium was measured at the same level in the pre- and post-implant images. The LAA long axes were positioned to allow visualization of the LAA orifice in the short axis. We measured 4 LAA orifice diameters: diameter 1 in the long axis, diameter 2 in its orthogonal view, and the minimum and maximum diameters in the short axis. Circumference and orifice area were also measured in the short axis. Eccentricity index was calculated as maximum/minimum diameter ratio to assess the LAA orifice geometry. An eccentricity index = 1 represents a perfect circle.(13) Measurements were taken at end-systole because LAA orifice dimensions are greatest in this cardiac cycle phase.(16)

We investigated the reproducibility of 3D analysis of LAA orifice in 10 randomly selected images (5 images pre- and 5 post- device placement). Measurements were done by a first observer blinded to initial measurements one month apart and by a second independent observer blinded to measurements obtained by the first observer.

Statistical Analysis

Categorical variables were expressed as numbers and percentages, and continuous variables were expressed as means ± standard deviations or median and interquartile range (IQR) according to their distribution. Comparisons of continuous variables pre- and post- Watchman placement were done using the paired Student’s t-test. Comparisons between groups were done using Student’s t-test or the Mann-Whitney U test. The intraclass correlation coefficient (ICC) and their 95% confident intervals (CI) were estimated to assess intra- and inter-observer variability of 3D measurements of LAA orifice. Statistical significance was determined by a p-value < 0.05. Statistical analysis was performed using IBM SPSS Statistics software, version 23.

Results

Patients’ demographics characteristics are summarized in Table 1. Patients were elderly (mean age 76 ± 8 years) and the majority (60%) were men who had paroxysmal AF (52%). The most frequent comorbidities were hypertension (84%), hyperlipidemia (68%), and smoking (70%). All patients had a CHAD₂DS₂-VASc score ≥ 2 (mean 4.4 ± 1.5) and the HAS-BLED score ranged between 1–5 (mean 2.7 ± 0.9). Most patients (60%) were receiving non–vitamin K antagonist oral anticoagulants as antithrombotic therapy.

Table 1. Baseline characteristics (N=50)

Variable	Value
Age (years)	76±8
Male, n (%)	30 (60)
Body mass index (kg/m ²)	29.2±4.4
Body surface area (m ²)	1.99±0.26
Heart rate (bpm)	73±14
Systolic Blood Pressure (mmHg)	132±33
Diastolic Blood Pressure (mmHg)	73±14
Smoking, n (%)	35 (70)
Diabetes, n (%)	19 (38)
Hypertension, n (%)	42 (84)
Hyperlipidemia, n (%)	34 (68)
Chronic obstructive pulmonary disease, n (%)	7 (14)
Chronic kidney disease, n (%)	13 (26)
History of stroke or transit ischemic attack, n (%)	17 (34)
Type of Atrial fibrillation	
Paroxysmal, n (%)	26 (52)
Persistent, n (%)	9 (18)
Long-standing persistent, n (%)	5 (10)
Permanent, n (%)	10 (20)
CHA ₂ DS ₂ -Vasc Score	
2	5 (10)
3	11 (22)
4	11 (22)
5	9 (18)
6	9 (18)
7	5 (10)
Antithrombotic therapy	
NOAC, n (%)	30 (60)

Warfarin, n (%)	4 (8)
Aspirin, n (%)	16 (32)
Data are presented as mean $\pm$ standard deviation, or n (percentage). NOAC: non-vitamin K antagonist oral anticoagulants.	

The distribution of implanted device sizes was as follows: 21 mm device in 5 patients (10%), 24 mm device in 16 patients (32%), 27 mm device in 13 patients (26%), 30 mm device in 7 patients (14%) and 33 mm device in 9 patients (18%).

Three-dimensional measurements of the LAA orifice were feasible in 50 of 52 (96%) patients. As shown in Fig. 2, there was a significant increase of all dimensions of the LAA orifice following LAA occlusion with the Watchman device: diameter 1 (pre-device 18.1 ± 3.2 vs. post-device 21.5 ± 3.4 mm, $p < 0.001$), diameter 2 (20.6 ± 3.9 vs. 22.1 ± 3.6 mm, $p < 0.001$), minimum diameter (17.6 ± 3.1 vs. 21.3 ± 3.4 mm, $p < 0.001$), maximum diameter (21.5 ± 3.9 vs. 22.4 ± 3.6 mm, $p = 0.022$), circumference (63.6 ± 10.7 vs. 69.6 ± 10.5 mm, $p < 0.001$), area (3.1 ± 1.1 vs. 3.9 ± 1.2 cm², $p < 0.001$).

The percent increase was 18.8% for diameter 1, 7.3% for diameter 2, 21.0% for minimum diameter, 4.2% for maximum diameter, 9.4% for circumference and 25.8% for area. We compared the percent increase in area -the LAA orifice dimension that showed the greatest percentage increase after the Watchman implant- according to the AF type and the implanted device size. The percent increase in area was not statistically different in patients with paroxysmal AF than in those with other types of AF (22.8%, IQR: 12.4–52.5 vs. 17.5%, IQR: 4.6–31.3, $p = 0.114$); and it was similar in patients who received larger Watchman devices (27, 30 and 33 mm) than in those who received smaller devices (21 and 24 mm) (20.0%, IQR: 12.8–34.5 vs. 18.7%, IQR: 7.8–45.0, $p = 0.989$).

Eccentricity index decreased and showed a value closer to 1 after device placement (pre-device 1.23 ± 0.16 vs. post-device 1.06 ± 0.06 , $p < 0.001$), which means that the LAA orifice changed from an ellipsoid geometry to a more circular shape.

As shown in Fig. 3, there was no significant difference in the LUPV peak S velocity pre and post LAA occlusion (0.29 ± 0.15 vs. 0.30 ± 0.14 cm/s, $p = 0.637$) nor in the peak LUPV peak D velocity (0.47 ± 0.19 vs. 0.48 ± 0.20 cm/s, $p = 0.549$).

Table 2 shows the results of the reliability analysis of 3D measurements of LAA orifice. Intra-observer reliability was good to excellent for diameter 1, and excellent for diameter 2, minimum diameter, maximum diameter, circumference, and area. Inter-observer reliability was good to excellent for all parameters. Table S1 in the Supplementary Material shows the reliability analysis separating the pre- and post-device measurements. Intra-observer agreement was better in the post-device measurements, mainly for diameter 1 and minimum diameter, while the inter-observer agreement was better in the pre-device measurements.

Table 2. Intra- and Inter-Observer Variabilities in 3D Measurements of LAA orifice

LAA orifice parameters	Intra-observer reliability	p value	Inter-observer reliability	p value
Diameter 1	0.97 [0.89-0.99]	<0.001	0.97 [0.87-0.99]	<0.001
Diameter 2	0.98 [0.91-0.99]	<0.001	0.97 [0.86-0.99]	<0.001
Minimum diameter	0.98 [0.90-0.99]	<0.001	0.97 [0.88-0.99]	<0.001
Maximum diameter	0.97 [0.90-0.99]	<0.001	0.95 [0.82-0.99]	<0.001
Circumference	0.98 [0.95-0.99]	<0.001	0.96 [0.83-0.99]	<0.001
Area	0.99 [0.97-0.99]	<0.001	0.97 [0.86-0.99]	<0.001
Data are presented as intraclass correlation coefficient [95% confidence intervals]. LAA: left atrial appendage.				

Peri-device leak was noted in 11 (22 %) patients, all size ≤ 2 mm. The post-device eccentricity index tended to be higher, meaning a more circular LAA orifice, in patients with peri-device leak compared with those without leak although the difference was not statistically significant (1.07 ± 0.10 vs. 1.05 ± 0.05 , respectively, $p = 0.319$).

Discussion

In this study, we assessed the dimensions and geometry of the LAA orifice pre- and immediately post-implantation of the Watchman device using 3D echocardiography. Furthermore, we compared the physiology of the LUPV by measuring its velocities. Our study found: 1) significant stretching of the LAA orifice following implantation of the device, 2) the LAA orifice geometry changed from an oval to a more circular shape, and 3) the LAA occlusion did not have a significant impact on the LUPV hemodynamics.

As has been demonstrated in previous pathological studies (17, 18) and through the 3DE evaluation of LAA,(14) the shape of the LAA orifice is consistently elliptical rather than circular. Current percutaneous closure devices, however, have a circular shape to fill or cover the ostium. When implanting a circular device over an oval orifice, the device must be oversized to achieve complete occlusion and avoid device dislodgement. This oversizing can have an impact on the dimensions and geometry of the LAA, as we observed in this study. Our results showed that there was a significant increase in the dimensions of the LAA orifice with an average percentage increase of 25.8% of its area independent of the type of AF and the size of the implanted device. Because the LAA is a very flexible structure and its ostium must seat a

circular device, the LAA orifice can be expected to change from an oval to a more circular shape, as our results demonstrated (Fig. 1D). The change in LAA orifice geometry towards a more circular shape with the implanted device could prevent the presence of peri-device leaks and likely explains the low prevalence of peri-device leaks we found (22%) which was lower than previously reported.(10, 19) The finding that patients without peri-device leak tended to have a lower post-device eccentricity index, that is, a more circular LAA orifice, when compared to those with peri-device leak supports this theory. All leaks were not significant (< 5mm) according to previously accepted definition(20).

For successful percutaneous LAA occlusion and to avoid any complications, it is necessary to take into account not only the anatomy of the LAA but its spatial relationship to neighboring structures.(10) Oversizing the device runs the risk of overlapping or impinging upon neighboring structures, including the left pulmonary veins, the coronary arteries, and the mitral valve.

The LAA orifice is in close proximity to the LUPV, the mean distance between the rim of the ostium and the LUPV was 11.1 ± 4.1 mm in an autopsy study,(18) therefore, there is a potential risk of LUPV compression when the LAA is occluded with any percutaneous device.

In a study that assessed the effects of the PLAATO (percutaneous left atrial appendage transcatheter occlusion) device, no evidence of disruption to pulmonary vein inflow or mitral valve function was found. (21) On the other hand, there is a report of a patient who developed compression around 50 percent of the left inferior pulmonary vein following LAA occlusion with an Amplatzer cardiac plug device. (8) In our cohort, the Watchman device had no impact on the functional integrity of the LUPV even though the LAA orifice showed significant expansion, which supports the previous findings reported in a study carried out in a canine model.(6) In this animal study, it was observed that the Watchman device did not obstruct or affect the LAA adjacent structures, resulting in a favorable surface recovery. On the other hand, the oversized Amplatzer Cardiac Plug device could potentially jeopardize the LAA neighboring structures and lead to delayed healing.

A new-generation Watchman FLX device has recently been introduced. Compared to the previous generation of Watchman that was used in this study, the Watchman FLX device can treat both smaller and larger LAA ostia (ranging from 14 to 31.5 mm) and it is 10 to 20% shorter in length enabling implantation even in shallow LAAs.(22) Studies that include the use of this new device are needed to understand how its design impact the dimensions and shape of the LAA orifice and its neighboring structures.

Limitations

The limitations of this study include that we only evaluated the impact of LAA occlusion with a single percutaneous device, since it is the only one that is implanted in our center, therefore the results cannot be extrapolated to the other percutaneous devices available worldwide. Second, we measured the changes in LAA only immediately after device implantation, however, due to the healing and remodeling process these changes may be different in the long-term follow-up. Third, our study population was relatively

small and we only included those patients with 3D images available, leading to selection bias. Finally, the effect of the changes of the LAA orifice geometry on left atrial function remains unknown.

Conclusion

Our study shows that LAA occlusion with the Watchman device modifies the geometry and stretches the LAA orifice significantly becoming more circular following but does not result in any detrimental hemodynamic changes of the adjacent LUPV.

Declarations

Funding: No funding was received.

Conflicts of interest/Competing interests: Dr. Sugeng has received a research grant from and is a speakers' bureau member for Canon Medical; has received a research grant from and is a speakers' bureau and advisory board member for Siemens Healthineers; has received a research grant from and is an advisory board member for Philips Healthcare; and has received an equipment grant from and is a speakers' bureau member for Hitachi. The other authors reported no conflicts of interest.

Availability of data and material: The data underlying this article will be shared on reasonable request to the corresponding author.

Code availability: Not applicable.

Authors' contributions: Conceptualization: Lissa Sugeng. Methodology: Edith L. Posada-Martinez, Alda Bregasi, Wanwen Chen, Ian Crandall, Jason Pereira, Joseph G. Akar, Ben A. Lin MD, James V. Freeman, Jephtha Curtis and Xochitl A. Ortiz-Leon. Formal analysis and investigation: Edith L. Posada-Martinez and Xochitl A. Ortiz-Leon; Writing - original draft preparation: Xochitl Ortiz; Writing - review and editing: Kamil F. Faridi and Lissa Sugeng. Supervision: Robert L. McNamara, Jose A. Arias-Godinez and Lissa Sugeng.

Additional declarations for articles in life science journals that report the results of studies involving humans and/or animals: Not applicable.

Ethics approval (include appropriate approvals or waivers): The study was approved by the Yale University Institutional Review Board.

Consent to participate (include appropriate statements): Consent was not required due to retrospective analysis of anonymized information and ultrasound images and the submission does not include images that may identify the patients.

Consent for publication: Not applicable.

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Figures

Figure 1

Three-dimensional acquisition of the left atrial appendage (LAA) at baseline prior to LAA closure and post device placement (A and B). In an en-face orientation of the left atrial appendage prior to closure (panel C), the LAA orifice appears oval, post Watchman (D) the LAA appears has increased in size and assumes the shape of the device.

Figure 2

How to perform the measurements on the multiplanar reconstruction using 4D-Cardio View software (TomTec). The green plane (blue arrow) was placed on the inferior rim of the LAA ostium at the level of the Left Circumflex coronary (Cx) to the same point distal from the tip of the Coumadin ridge in the images pre (A) and (B) post-Watchman placement to ensure that the LAA ostium was measured at the same level. Diameter 1 (D1) is the orifice diameter measured in the long axis and diameter 2 (D2) is the orifice diameter in its orthogonal view. Minimum and maximum diameters, circumference, and area were measured in the short axis. LAA: left atrial appendage.

Figure 3

Comparison of 3DE measurements of the LAA orifice and LUPV peak S and D velocities pre- and post-Watchman placement. 3DE: Three-dimensional echocardiography. LAA: Left atrial appendage.

Supplementary Files

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