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Imaging (Q Truong, Section Editors)

Pre and Post Procedure Imaging of the Watchman® Device with Cardiac Computed Tomography Angiography

Dennis Toy, MD[1,*]
David M. Naeger, MD[2]

Address
[*,1]Department of Radiology, Weill Cornell Medicine, 525 E. 68th Street, Box 141, New York, NY, 10065, USA
Email: Det9069@med.cornell.edu
[2]Denver Health, Department of Radiology, University of Colorado, 777 Bannock St. MC0024, Denver, CO, 80204, USA

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Abstract

Purpose of review Left atrial appendage occlusion with the Watchman® device requires pre and post procedure imaging. Currently, transesophageal echocardiography is the recommended modality, though cardiac computed tomography angiography may be an acceptable alternative.
Recent findings Cardiac computed tomography angiography can be used to safely and accurately predict Watchman® device sizing. It can also be used to detect post procedure complications similar to, or better than, transesophageal echocardiography.
Summary Cardiac computed tomography angiography is a viable alternative imaging modality for pre and post procedure evaluation for the Watchman device.

Introduction

In patients with non-valvular atrial fibrillation, the majority of thrombus has been associated with the left atrial appendage (LAA) [1]. Thus, percutaneous isolation of the LAA from systemic circulation has been a topic of research for treatment, especially in patients with contraindications for long-term anticoagulation. The recent

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publication of the 2-year outcomes from the EWOLUTION registry demonstrated that the real-world use of the Watchman® device is associated with decreased stroke, TIA, and systemic embolism events despite the highly variable use of post deployment anticoagulation [2••]. These encouraging results will likely increase the use of the device, especially in patients with contraindications to anticoagulation.

Imaging evaluation plays an important role both pre procedurally (to determine patient eligibility and sizing for the device) and post procedurally (to monitor for device-related complications).

Current device manufacturer guidelines recommend transesophageal echocardiogram (TEE) for pre and post procedure imaging [3]. However, TEE is an invasive procedure that requires at least moderate sedation [4]. It is also subject to operator dependence and requires patients to fast. Fasting can lead to subsequent volume depletion, which has been associated with a decreased LAA width of approximately 10%. This could potentially lead to incorrect device size selection [5]. TEE also requires substantial time commitment from patients.

In comparison with TEE, cardiac computed tomography angiography (CCTA) offers a compelling alternative modality for both pre and post procedure imaging assessment. Advances in technology have allowed for lower radiation doses with excellent spatial and temporal resolution. Pre procedure CCTA is associated with better accuracy than TEE. Post procedure imaging processing allows for detailed evaluation of the left atrial appendage anatomy and adjacent structures [6]. Further, it does not require as much procedure time or patient fasting.

Watchman device procedure review

To place the Watchman device, vascular access is obtained via the femoral vein. A transseptal puncture is performed to gain access to the left atrium and left atrial appendage. Next, a delivery sheath is advanced into the left atrial appendage. Device size is selected based on maximal landing zone diameter of the left atrial appendage using pre procedure measurements and confirmed with intra-procedural transesophageal echocardiogram (TEE) and fluoroscopic imaging.

Pre procedure imaging with CCTA

The goal of pre procedure imaging is to determine whether the left atrial appendage is suitable for intervention and to exclude possible contraindications to the procedure. This includes a detailed evaluation of the LAA morphology, LAA measurements and device sizing, and evaluation for thrombus and other pertinent imaging findings. These are discussed below in greater detail.

Currently, there is no standardized CCTA protocol for LAA occlusion planning. Protocols vary by institution: e.g., some institutions use retrospective gating to obtain more of the cardiac cycle while others use prospective gating with an R-R′ interval selected for about 35–45 [7•]. If multiple phases are obtained, the phase selected for measurement should be mid to late left ventricular systole, which typically corresponds with maximum left atrial diastole. This would result in the left atrium (and, consequently, the LAA) being its maximum size for the purposes of determining maximum LAA measurements and subsequently appropriate device size. A delayed phase scan should be included to evaluate for LAA thrombus. The field of the view for the delayed images can be narrowed to include just the LAA to help reduce radiation [8, 9].

Left atrial appendage morphology

The left atrial appendage (LAA) is a blind-ending tubular outpouching arising from the body of the left atrium [10]. Though small, it is a complex structure with a highly variable appearance [11]. Its role as a frequent nidus of thrombus formation in patients with atrial fibrillation, and potential site of intervention, has led to detailed evaluations of its anatomy.

Several classification systems have been proposed to categorize the LAA. The system devised by Lacomis et al. subdivides the LAA into 3 categories based on the location and orientation of the LAA tip [12]. In type I, the tip is directed superiorly and runs parallel to the main pulmonary artery (MPA) and left heart border. In type II, the tip is directed inferiorly and runs parallel to the MPA and left heart border. In type III, the tip is directed superiorly and medially, coursing between the MPA and left atrial body, i.e., retropulmonic.

Another commonly used classification system (devised by Wang et al.) divides the LAA based on morphology. Subgroups in descending order of prevalence include chicken wing, cactus, windsock, and cauliflower [13]. Certain morphologies have been associated with increased risk of thrombus. In one study, patients with the "cauliflower" subtype were eight times more likely to have a stroke or transient ischemic attack compared with patients with the "chicken-wing" subtype [14].

Despite the arbitrary nature of the classification systems, when used consistently, they provide a common framework to describe a highly variable structure. Pre procedure imaging assessment should attempt to categorize the LAA using one or both systems.

Left atrial appendage measurements and device sizing

CCTA has been shown to safely and accurately predict device sizing compared with TEE. Compared with TEE, LAA measurements obtained from CCTA correlate more strongly with size of the final device deployed [7•]. Other studies confirm appropriate device sizing with CCTA measurements ranging from 83 to 100% accuracy, compared with 38–47% for 2D and 3D TEE respectively. Accuracy is based on the ability to correctly predict size of the device ultimately deployed [15, 16••]. Maximal LAA dimensions with CCTA are often larger and more accurate than those measured by pre procedure 2D and even 3D TEE [15, 16••]. This suggests that using TEE alone may lead to initial selection of an inappropriately smaller device. The tendency to underestimate ostial dimensions using TEE may be related to a combination of technical differences in imaging modality as well as physiological differences such as the fasting requirements of TEE.

An important component of determining patient eligibility for the procedure is the LAA "landing zone" measurements. The landing zone is the predicted location where the device shoulder should be seated for proper LAA occlusion. The landing zone and the anatomic LAA ostium are not necessarily the same. Methods to determine the landing zone have been discussed in greater detail elsewhere [16••]. A landing zone maximum diameter which is too small or too large may preclude device placement.

The short axis view of the landing zone is used to measure the maximum and minimum diameters, circumference, and area. In this view, the landing zone is typically oval in shape. In the coronal or sagittal plane, the maximum

length from the landing zone plane to the tip of the LAA is measured. This distance is necessary to determine whether the LAA is of sufficient length to accommodate the device. The device length is approximately equal to the device diameter (i.e., it is acorn-shaped). Thus, the distance from the landing zone to the tip of the LAA must be equal or greater than the maximum diameter of the landing zone. An insufficient depth risks perforation.

Appropriate device sizing helps to ensure that the device remains in place after deployment. Undersizing could lead to device embolization and peri-device leak. Oversizing could lead to rupture.

The device is currently available in 5 sizes: 21, 24, 27, 30, and 33 mm. Device selection is based on the maximum diameter of the LAA landing zone. Please refer to Table 1. The smallest acceptable landing zone diameter being 17 mm and the largest is 31 mm. For example, a LAA maximum diameter of 24 mm would correspond with a size 27 mm Watchman.

While pre procedure imaging will guide initial device selection, intra-procedure TEE and angiography of the LAA will be used to ensure the device is seated properly.

Evaluation for LAA thrombus and other pertinent imaging findings

Evaluation of the LAA should include whether thrombus is absent or present. Thrombus within the LAA is a contraindication for device placement as manipulation of the thrombus with a catheter could potentially result in embolization of the clot. In one study, acquiring delayed images on CT resulted in a positive and negative predictive value of 93% and 100%, respectively, for the presence of thrombus [8]. The delayed phase helps to eliminate slow flow within the LAA as a potential false positive. Thus, it may be prudent to include delayed imaging of the LAA despite the increase in radiation dose.

Of note, the endocardial surface of the LAA is lined by multiple pectinate muscles running in parallel ridges. This gives the LAA a trabeculated appearance [17]. Increased trabeculation has been associated with increased risk of stroke [18]. When prominent, the pectinate muscles can be mistaken for thrombus on echocardiography and CT [8, 19].

The presence or absence of a pericardial effusion should also be reported. Serious pericardial effusions, defined as requiring pericardiocentesis or surgical intervention, were the most common adverse events in the PROTECT AF trial [20]. While a pericardial effusion is not an absolute contraindication for device placement, it may be important for post procedure monitoring.

Table 1. Device size. Suggested size is based on maximum left atrial appendage landing zone diameter

Maximum LAA landing zone (mm)	Device size (mm)
17–19	21
20–22	24
23–25	27
26–28	30
29–31	33

Atrial septal defect (ASD) and patent foramen ovale (PFO) repairs should be reported as well. The procedure involves transseptal puncture and a prior ASD or PFO repair may complicate the procedure. While there are case reports of successful implantation of the device in patients with prior ASD repair, history of a prior ASD or PFO repair remain listed as contraindications [3, 21].

Post procedure imaging with CCTA

After device placement, follow-up imaging is advised to evaluate for potential issues, primarily device-related thrombosis (DRT), peri-device leak (PDL), and incomplete endothelialization. Findings described on post procedure imaging can significantly alter patient management in terms of medication administration or the need for more frequent or additional follow-up imaging.

Current manufacturer guidelines for the Watchman® device recommend patients be discharged with warfarin and aspirin. A transesophageal echocardiogram (TEE) is performed 45 days post procedure to evaluate for intracardiac thrombus, peri-device leak > 5 mm, and device-related thrombosis. In the absence of these findings, warfarin is discontinued and clopidogrel is administered for the next 6 months and discontinued thereafter. Aspirin is maintained indefinitely. A follow-up TEE is performed 12 months after device placement to confirm the absence of the above findings [3].

When device-related issues are present, the manufacturer defers to physicians to determine whether changes in medication are needed and when to perform follow-up imaging. While there are currently no standardized treatment or follow-up imaging guidelines for PDL or DRT, some physicians familiar with the use of the Watchman® advocate a combination of intensifying or continuing medication along with more intense surveillance imaging. One paper suggests repeat imaging every 6–12 weeks for PDL and 8–12 weeks for DRT [22••]. The decision to modify or continue medication should be weighed carefully against the increased risk of bleeding.

The burdens imposed by TEE may result in reduced compliance and increased risk to the patient arising from the procedure itself. Specifically, TEE comes with inherent procedural risks, is uncomfortable, and requires fasting and moderate anesthesia. In one study, the authors found that only 72% of patients complied with the recommended 12-month follow-up [23]. The authors attribute this finding to an already frail patient population among other reasons. If more frequent follow-up imaging is required, compliance may likely be worse [24]. A real-world population may exacerbate these effects.

Some authors have suggested CCTA as a viable alternative for standard post procedure imaging [25]. Given TEE imposes substantial patient burdens, CCTA would be particularly beneficial for patients unable to tolerate TEE. This would be certainly true in the setting of increased imaging [24]. CCTA requires less time for preparation and imaging, no anesthesia or fasting, and is more comfortable for patients. Despite these strong potential advantages, stronger endorsement for the use of CCTA is likely limited by available studies having small sample size and an overall lack of studies directly comparing CCTA with TEE. Nevertheless, the studies that are available suggest that CCTA can be used to evaluate for PDL and DRT with equal or better sensitivity than TEE [25, 26]. In fact, some authors use

CCTA as the primary routine imaging modality for follow-up at their respective institutions [25].

The next few sections will discuss the use of CCTA in evaluating device-related thrombosis (DRT), peri-device leak (PDL), and incomplete endothelialization.

Device-related thrombosis

Left atrial appendage occlusion devices are intrinsically thrombogenic. Thrombus forming behind an occluder is of course expected and intended. It is due largely to stasis of blood post occlusion. Clot formation on the surface of the device facing the left atrium is not intended and is known as device-related thrombosis (DRT). Warfarin and aspirin help to reduce thrombus formation while neo-endothelialization occurs along the atrial surface of the device.

Overall, the incidence of DRT has been reported at 3 to 7% [23, 27]. Some studies found that the presence of DRT increases the risk of non-ischemic strokes and transient ischemic attacks [23, 28••]. However, a more recent analysis showed that the rate of stroke/TIA between patients with and without DRT was not significantly different [2••].

Thrombus may form anywhere along the device, though it is usually seen attached to the center screw's exposed metal or along the device edge [22••, 28••, 29, 30] (see Fig. 1). On CCTA, DRT appears as focal hypoattenuating material on the atrial surface of the device. In one retrospective study, there was no difference between CCTA and TEE in the detection of device-related thrombosis [23].

Several studies have attempted to determine predisposing factors for DRT. Patients with a prior history prior of stroke/TIA, permanent atrial fibrillation, vascular disease, and larger LAA diameters were more likely to have DRT [28••]. Another factor that may predispose to thrombus formation is the device being unusually deeply seated. One group of authors defined that as when the entire

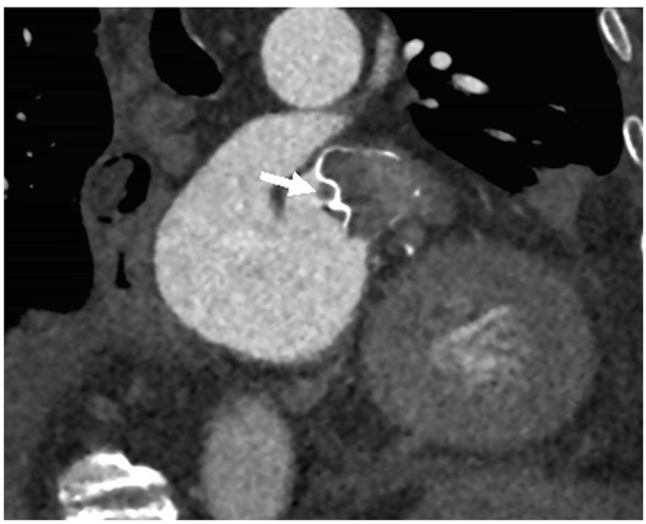

Fig. 1. Device-related thrombosis. Note the low-density material (arrow) attached to the center screw of the device. Thrombus can occur along the atrial surface of the device and is a known complication. Clot along the appendage side of the device and within the LAA is the intent of the device, and is therefore expected.

device is located below the LAA ostial plane [31]. This leads to creation of a residual LAA or neo-LAA, which may cause stagnation of blood flow, thereby leading to thrombus formation. A deep-seated device can be readily assessed on imaging.

No standardized treatment guidelines exist for DRT. The general consensus is to reinitiate or intensify anticoagulation. One study reported complete resolution of DRT in all cases after resuming warfarin while another reported 95% of thrombi resolving [29, 32]. Cases of DRT in which anticoagulation is not feasible or has failed, large thrombus, or there are recurrent thromboembolic events, surgical excision can be considered [22••]. Of note, in one study, DRT resolved without treatment in 9 out of 13 patients [2••].

In diagnosed cases of DRT, there are no standardized imaging follow-up guidelines. Some authors advocate follow-up imaging 8–12 weeks after initiating treatment of DRT and again at 3–6 months after documented resolution [22••]. Given the frequency of required imaging and overall accuracy, CCTA is a reasonable modality for serial follow-up imaging.

Peri-device leak

While the Watchman® device comes in several sizes, the occlusive surface for each size is circular in shape. This poses a unique challenge in occluding LAAs, since the ostia and landing zone can vary in size and shape [13]. Despite careful sizing and patient selection, incomplete sealing of the left atrial appendage can occur, resulting in a gap between the chamber wall and the device. The incomplete apposition permits continuous, albeit reduced, communication between the left atrium and LAA and is known as peri-device leak (PDL) or peri-device flow (PDF).

Peri-device leak is a common post procedure finding with reported incidences ranging up to 71% [26]. Evaluation and grading of PDL severity was originally described using color Doppler techniques to evaluate for peri-device flow on follow-up TEE with initial LAA occluder devices [33]. By current standards, the deployment is deemed a technical success if the width of the communicating flow jet is ≤ 5 mm [34].

CCTA can be used to directly visualize the PDL gap. The space between the device and the LAA wall is measurable, ideally by using multiplanar reconstruction techniques [35]. An additional finding to support the presence of PDL is increased opacification of the LAA (above that of unopacified blood), indicating that the contrast administered for the CTA has reached the LAA through the gap. This finding may be more apparent on delayed images. Although the exact HU values will vary based on individual scan parameters, a well occluded LAA often measures < 100 HU [25].

A few studies have concluded that CCTA is more sensitive than TEE in detecting PDL [25, 26]. One study defined PDL on CCTA as increased opacification of the LAA regardless of whether a peri-device gap was visualized [26]. However, with recent literature reporting cases of incomplete endothelialization well beyond the expected 45 days, it is unclear whether the increased sensitivities on CCTA are truly cases of PDL or whether they are incorporating false positives from incomplete endothelialization, which would allow contrast to flow through the device's

membrane. Incomplete endothelialization is discussed in a separate subsection below. Regardless, this confounding situation underscores the need for standardized definitions of PDL that encompass multiple modalities.

While CCTA allows for a repeatable measurement of the PDL gap, more research is needed to determine whether the gap distance and jet flow width on TEE are comparable measurements.

A main theoretical concern regarding PDL is a LAA thrombus escaping through the gap, leading to a thromboembolic event. Despite this theoretical risk, no association between the presence of PDL and an increased risk of thromboembolism has been shown [26, 27]. Indeed, the hazard ratio for thromboembolic events was similar across PDL of different sizes [27]. The above evaluations may be somewhat limited by low power, leaving the possibility of a small, but real, increased risk.

Current manufacturer guidelines suggest that warfarin can be safely discontinued if the PDL ≤ 5 mm. In the presence of a PDL > 5 mm, treatment and follow-up are deferred to the treating physician's discretion. While standardized guidelines for treatment and imaging do not exist, some authors recommend continuing anticoagulation with repeat imaging in 6–12 weeks [22••]. Again, the decision to alter or continue medication should be weighed against the increased risk of bleeding.

Incomplete endothelialization

The Watchman® device is composed of a self-expanding nitinol frame with a permeable membrane covering. Post placement, neo-endothelialization occurs over the membrane. This reduces the thrombogenicity of the device while also making the membrane impermeable to blood flow. Animal models show endothelial cells cover most of the membrane within 28–45 days, with complete endothelialization by 90 days [36, 37].

Complete endothelialization does not always occur within the aforementioned timeframes. A case report from 2012 describes incomplete endothelialization of a Watchman® device 10 months after placement [38]. More recent cases report incomplete endothelialization as far as 3 years after device deployment [39•, 40]. Characterization of incomplete reendothelialization is thus far limited to case reports on explanted devices.

Direct evaluation of the endothelium is not possible by CTA or ultrasound, but indirect findings on CCTA and TEE may be used to infer incomplete endothelialization. One paper proposes that residual opacification of the LAA on CCTA in conjunction with the absence of documented peri-device leak on TEE suggests underlying incomplete endothelialization [41•]. This supposition may be difficult to prove without a robust explant-based study, but the idea warrants further investigation. This topic also highlights the evolving and often confusing issues with discussing device complications. As previously mentioned, one paper used LAA opacification on CCTA as the definition of a PDL, whether or not a visible defect was present [26]. Thus, the high prevalence of PDL on CCTA may have been elevated by incorporating false positives from cases on incomplete endothelialization.

Further studies are needed to validate the combined use of CCTA and TEE to evaluate for incomplete endothelialization. Nevertheless, should incomplete

endothelialization be as prevalent as numbers suggest, it would significantly alter patient management and imaging follow-up.

Conclusion

Left atrial appendage occlusion with the Watchman device is an effective treatment for non-valvular atrial fibrillation to prevent stroke and other thromboembolic events, especially in patients with contraindications to long-term anticoagulation. Pre and post procedure imaging is a vital component for patient care. CCTA is a viable alternative to TEE in performing that imaging.

Compliance with Ethical Standards

Conflict of Interest
The authors declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent
This article does not contain any studies with human or animal subjects performed by any of the authors.

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Incomplete endothelialization is not fully understood but has potentially significant implications for the device. This study highlights the need for additional research and suggests a reasonable approach to assess for incomplete endothelialization.

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