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Research paper

Computed tomography measurement of the left atrial appendage for optimal sizing of the Watchman device

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ABSTRACT

Introduction: Percutaneous left atrial appendage (LAA) occlusion is an emerging treatment option for patients with non-valvular atrial fibrillation who cannot tolerate oral anticoagulation. The Watchman device (Boston Scientific Corporation, Natick, MA, USA) is deployed at the ostium of the LAA, and an appropriately sized device is critical for successful occlusion. However, standardized imaging protocols for device sizing have not been established.

Objectives: We investigated the clinical utility of a standardized imaging protocol, with pre-procedural multi-detector cardiac computed tomography (MDCT), and intra-procedural transesophageal echocardiography (TEE), for Watchman device sizing.

Methods: Patients who underwent Watchman device implantation between 2010 and 2016 at our center, and who had pre-procedural MDCT and intra-procedural TEE were included. MDCT measurements (CTmax, CTmin, CTmean), and TEE measurement (TEEmax) of the LAA ostium were determined for each case, and correlated with the final size of the Watchman device implanted. Demographic data and clinical outcomes were collected.

Results: The study included 80 patients (mean age: 75 ± 9.6 years; male: 68%; mean CHA2DS2-VASc score: 4.5 ± 1.4). CTmax of the LAA ostium correlated strongly with the final deployed Watchman device size (Spearman's rho: 0.81, $p < 0.001$), while TEEmax of the LAA ostium showed only moderate correlation with the final deployed Watchman device size (Spearman's rho: 0.61, $p < 0.001$). Implantation success rate was 100%. At a mean duration of follow-up of 197 days, there were no device-related complications (device embolization, cardiac perforation and pericardial tamponade). At follow-up, the vast majority of patients (76 patients; 95%) had either no or trivial (≤3 mm) residual peri-device leak on TEE.

Conclusions: A standardized imaging protocol for assessment of Watchman device implantation incorporating pre-procedural MDCT and intra-procedural TEE, was associated with excellent procedural outcomes at a mean duration of follow-up of 197 days.

1. Introduction

Percutaneous left atrial appendage (LAA) closure is an emerging treatment option for stroke prevention for patients with non-valvular atrial fibrillation (AF) who cannot tolerate oral anticoagulation.[1,2] The Food and Drug Administration approved the Watchman device (Boston Scientific Corporation, Natick, MA, USA) in the United States in March 2015 for stroke prevention in patients with non-valvular AF, who would have been recommended for oral anticoagulation, and who have an appropriate reason for a non-pharmacological alternative to warfarin, based on data from randomized trials.[3–6]

Manufacturer recommendations of Watchman device sizing are based on the maximum LAA ostium diameter obtained by transesophageal echocardiography.[7] Deployment of an appropriately sized Watchman device is important, because device under-sizing may result in device embolization and peri-device leak, and device over-sizing can lead to perforation of the LAA and cardiac tamponade.

Multi-detector cardiac computed tomography (MDCT) has been

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reported to be useful for the assessment of LAA morphology and anatomy.[8,9] Limited data are available on the correlation of TEE and MDCT measurements of the LAA ostium for percutaneous LAA closure. In particular, pre-procedural MDCT for the sizing of Watchman device has only been reported in a combined total of 50 patients from two recent studies.[10,11] Standardized imaging protocols for the assessment of LAA and Watchman device sizing have not been established. We investigated the clinical utility of pre-procedural MDCT in the assessment of LAA, and sizing of the Watchman device, correlating with intra-procedural TEE assessment, in a contemporary cohort of patients undergoing Watchman device implantation.

2. Methods

Patients who underwent Watchman device implantation at the Cleveland Clinic between 2010 and 2016, and who had pre-procedural MDCT and intra-procedural TEE were identified retrospectively. This study was approved by the Cleveland Clinic Institutional Review Board. Standard demographic, clinical and baseline transthoracic echocardiographic parameters, including left ventricular ejection fraction (LVEF), and left atrial volume index (LAVI) were collected.

MDCTs were performed with prospective systolic-triggered ECG-synchronized cardiac gating at 35–45% of the RR interval, corresponding to late atrial diastole, with: 1.) Philips 256-slice MDCT (Brilliance iCT, Phillips Healthcare, Cleveland, Ohio, United States); 2.) Siemens 128-slice dual-source MDCT (Somatom Definition Flash, Siemens Healthcare, Forchheim, Germany); and 3.) Siemens 192-slice dual-source MDCT (Somatom Force, Siemens Healthcare, Forchheim, Germany). Multi-planar reconstruction of the digital images were performed using Aquarius iNtuition (version 4.4.11, TeraRecon Incorporated, Foster City, California, United States).

Multi-planar reconstruction of MDCT data was performed in oblique planes with respect to conventional axial, coronal and sagittal planes, focusing on the LAA (Fig. 1). The ostium of the LAA was defined by the plane that connected between the base of the Coumadin ridge and the proximal left circumflex artery. The cross-section of the LAA ostium was created from orthogonal projections. The maximum (CTmax) and minimum (CTmin) LAA ostium diameters were measured from the cross-sectional image. CTmean was defined as the mean LAA ostium diameter assuming circularity of the LAA ostium (CTmean = LAA orifice perimeter/π). Intra-procedural TEE examinations were analyzed to obtain measurements of LAA ostium and depth at standard angles in mid-esophageal views (0°, 45°, 90°, 135°) recommended by the device manufacturer (Boston Scientific Corporation, Natick, MA, USA). CTmax, CTmin, CTmean and the maximum TEE measurement (TEEmax) of the LAA ostium were correlated with the final deployed Watchman device size.

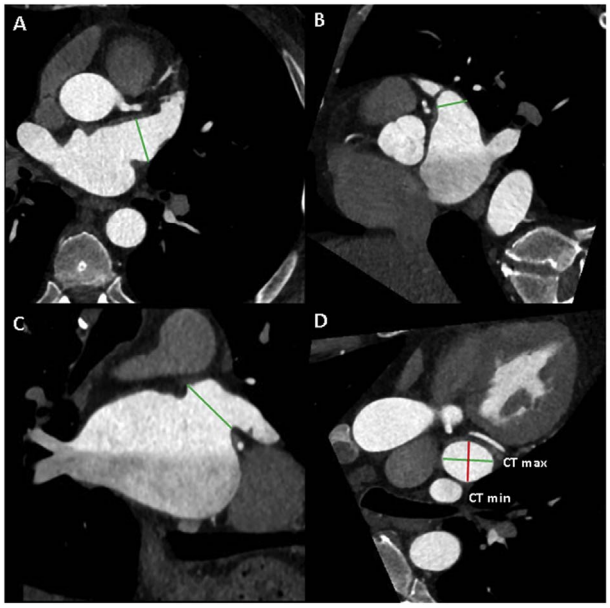

Fig. 1. Pre-procedural MDCT assessment of the LAA. The cross-section of the LAA ostium (D) was created from orthogonal projections (A, B, C). The maximum (CTmax) and minimum (CTmin) left atrial appendage ostium diameters were measured from the cross-sectional image (D).

Published manufacturer recommendations on Watchman sizing, which were based on TEE measurements of the LAA ostium, were used,[7] as follows:

- For a maximum LAA ostium in the range of 17–19 mm, the recommended Watchman device size is 21 mm;
- For a maximum LAA ostium in the range of 20–22 mm, the recommended Watchman device size is 24 mm;
- For a maximum LAA ostium in the range of 23–25 mm, the recommended Watchman device size is 27 mm;
- For a maximum LAA ostium in the range of 26–28 mm, the recommended Watchman device size is 30 mm;
- For a maximum LAA ostium in the range of 29–31 mm, the recommended Watchman device size is 33 mm.[7]

2.1. Watchman device implantation

All Watchman device implantations were performed by experienced electrophysiologists. Trans-septal puncture was achieved under intracardiac echocardiography and TEE guidance, following femoral venous access under general anesthesia. Unfractionated intravenous heparin was administered at a dose of around 80 international units/kilogram, aiming for an activated clotting time > 250 s. Left atrial pressure was measured for all patients to ensure it was greater than 12 mmHg. For patients with left atrial pressure less than 12 mmHg, intravenous hydration with normal saline was given. Watchman device was deployed under continuous TEE guidance by an experienced multimodality cardiovascular imaging cardiologist. The decision regarding the final Watchman device sizing for an individual patient was based on both pre-procedural MDCT assessment of the LAA, as described, in combination with intra-procedural TEE assessment. An experienced implanting electrophysiologist made the sizing decision for each patient, together with an experienced multimodality cardiovascular imaging cardiologist, who both independently reviewed the MDCT data prior to the procedure. Before the release of the Watchman device, the position of the device, the presence of any peri-device leak, and the degree of compression would be comprehensively assessed at standard angles in mid-esophageal views (0°, 45°, 90°, 135°) by TEE. A tug test was performed under TEE for each case to ensure stability of the device before final release. Left ventricular systolic function, left upper pulmonary venous flow, the pericardium, and the inter-atrial septum were carefully assessed following device deployment. All patients underwent routine transthoracic echocardiography the day following the procedure, to exclude procedural complications, such as pericardial effusion. All patients were maintained on oral anticoagulation and aspirin for six weeks. At six weeks, patients underwent post-procedural TEE to assess device positioning, stability and the presence of peri-device leak. For patients without a severe residual peri-device leak (≥5 mm), oral anticoagulation was stopped.

2.2. Intra- and inter-observer variability of MDCT and TEE measurements

Ten patients were randomly selected for intra- and inter-observer variability analysis. Three multimodality cardiovascular imaging cardiologists blinded to the results of LAA measurements by MDCT and TEE, and the size of the Watchman device deployed, measured the diameter of the LAA ostium for each patient twice (measurements were made from MDCT and TEE twice). Intra- and inter-observer variability